

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**218647Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

---

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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

---

|                                                           |                                            |
|-----------------------------------------------------------|--------------------------------------------|
| Date of This Review:                                      | March 16, 2025                             |
| Application Type and Number:                              | NDA 218647                                 |
| Product Name, Dosage Form, and Strength:                  | Hemiclor (chlorthalidone) tablets, 12.5 mg |
| Product Type:                                             | Single Ingredient Product                  |
| Rx or OTC:                                                | Prescription (Rx)                          |
| Applicant/Sponsor Name:                                   | PRM Pharma, LLC (PRM Pharma)               |
| PNR ID #:                                                 | 2025-1044726283                            |
| DMEPA 2 Safety Evaluator:                                 | Julie Neshiewat, PharmD, MS, BCPS, CPH     |
| DMEPA 2 Team Leader:                                      | Nicole Iverson, PharmD, BCPS               |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD                         |

---

## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Hemiclor, which was found unacceptable via a decision memo under NDA 218647 on July 8, 2024.<sup>a</sup>

### 1.1 REGULATORY HISTORY

PRM Pharma previously submitted the proposed proprietary name, (b) (4) \*\* under NDA 218647 on October 2, 2023. However, on December 29, 2023, we found the name, (b) (4) \*\* unacceptable due to orthographic and phonetic similarities and shared product characteristics with the proprietary names, (b) (4) and (b) (4). We also found (b) (4) \*\* unacceptable due to orthographic similarity and overlapping product characteristics with the currently marketed products (b) (4) and (b) (4).

PRM Pharma then submitted the proposed proprietary name, Hemiclor, on January 17, 2024. We initially found the name acceptable<sup>c</sup>, however via a decision memo the proposed proprietary name, Hemiclor, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) \*\*, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Hemiclor, was dependent upon which underlying application was approved first.

The underlying application for (b) (4) \*\* received a complete response on (b) (4) under BLA (b) (4). Thus, PRM Pharma resubmitted the proposed proprietary name, Hemiclor, for review on February 12, 2025 under NDA 218647.<sup>d</sup>

## 2 DISCUSSION

### 2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Hemiclor, DMEPA 2 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. We also evaluated previously identified names taking into account the change in dosage from (b) (4)

(b) (4) to (b) (4)

“Therapy should be initiated with the lowest possible dose. The recommended adult initial dose

<sup>a</sup> Iverson, N. Proprietary Name Review for Hemiclor (NDA 218647). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 JUL 08. PNR ID No. 2024-1044725572-1.

<sup>b</sup> Nalesnik, T. Proprietary Name Review for (b) (4) \*\*\* (NDA 218647). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 DEC 29. PNR ID No. 2023-10447255379.

<sup>c</sup> Mahmoud, S. Proprietary Name Review for Hemiclor (NDA 218647). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APRIL 16. PNR ID No. 2024-1044725572.

<sup>d</sup> Request for Proprietary Name Review (NDA 218647 Hemiclor. Villanova (PA): PRM Pharma, LLC; 2025 FEB 12. Available from: <\\CDSESUB1\EVSPROD\nda218647\0027\m1\us\m1-2-cover-letters\cover-letter.pdf>.

of HEMICLOR is (b) (4) given orally with food once daily. Double the dosage every 2 to 4 weeks as needed based on individual patient response, up to a maximum of 100 mg once daily. Dosage above 100 mg daily usually does not increase effectiveness.” Additionally, DMEPA 2 searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The February 18, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Based upon our safety assessment of the proposed proprietary name, Hemiclor, the application goal date for NDA 218647, and the status of the underlying application for (b) (4) \*\*, we find Hemiclor conditionally acceptable.

## 2.2 COMMUNICATION OF DMEPA’S DETERMINATION

On March 16, 2025, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

## 3 CONCLUSION

We conclude that the proposed proprietary name, Hemiclor, is conditionally acceptable.

### 3.1 COMMENTS TO PRM PHARMA, LLC

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

If any of the proposed product characteristics as stated in your submission, received on February 12, 2025, are altered prior to approval of the marketing application, the proprietary name 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/  
-----

JULIE V NESHIEWAT  
03/17/2025 09:44:31 AM

NICOLE F IVERSON  
03/17/2025 09:56:17 AM

HINA S MEHTA  
03/17/2025 10:04:17 AM

---

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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

---

|                                                         |                                            |
|---------------------------------------------------------|--------------------------------------------|
| Date of This Review:                                    | April 16, 2024                             |
| Application Type and Number:                            | NDA 218647                                 |
| Product Name, Dosage Form, and Strength:                | HemiClor (chlorthalidone) tablets, 12.5 mg |
| Product Type:                                           | Single Ingredient Product                  |
| Rx or OTC:                                              | Prescription (Rx)                          |
| Applicant/Sponsor Name:                                 | PRM Pharma, LLC (PRM Pharma)               |
| PNR ID #:                                               | 2024- 1044725572                           |
| DMEPA 2 Safety Evaluator:                               | Sali Mahmoud, PharmD, BCPS                 |
| DMEPA 2 Team Leader (Acting):                           | Nicole Iverson, PharmD, BCPS               |
| DMEPA 2 Associate Director for Nomenclature & Labeling: | Hina Mehta, PharmD                         |

---

## Table of Contents

|       |                                                                                                 |    |
|-------|-------------------------------------------------------------------------------------------------|----|
| 1     | INTRODUCTION .....                                                                              | 4  |
| 1.1   | REGULATORY HISTORY .....                                                                        | 4  |
| 1.2   | PRODUCT INFORMATION .....                                                                       | 4  |
| 2     | Discussion .....                                                                                | 5  |
| 2.1   | MISBRANDING ASSESSMENT .....                                                                    | 5  |
| 2.2   | SAFETY ASSESSMENT .....                                                                         | 5  |
| 2.2.1 | United States Adopted Names (USAN) Search .....                                                 | 5  |
| 2.2.2 | Components of the Proposed Proprietary Name .....                                               | 5  |
| 2.2.3 | Comments from Other Review Disciplines at Initial Review.....                                   | 6  |
| 2.2.4 | FDA Name Simulation Studies .....                                                               | 6  |
| 2.2.5 | Phonetic and Orthographic Computer Analysis (POCA) Search Results .....                         | 6  |
| 2.2.6 | Names Retrieved for Review Organized by Name Pair Similarity .....                              | 6  |
| 2.2.7 | Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities ..... | 7  |
| 2.2.8 | Communication of DMEPA's Determination .....                                                    | 8  |
| 3     | CONCLUSION .....                                                                                | 8  |
| 3.1   | COMMENTS TO PRM Pharma, LLC.....                                                                | 8  |
| 4     | REFERENCES.....                                                                                 | 9  |
| 5     | APPENDICES.....                                                                                 | 10 |



## 1 INTRODUCTION

This review evaluates the proposed proprietary name, HemiClor, 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. PRM Pharma submitted an internal analysis for this proposed proprietary name.

### 1.1 REGULATORY HISTORY

PRM Pharma previously submitted the proposed proprietary name, (b) (4) \*\* under NDA 218647 on October 2, 2023. However, on December 22, 2023, we found the name, (b) (4) \*\*\* unacceptable due to orthographic and phonetic similarities and shared product characteristics with the proprietary names, (b) (4) and (b) (4). We also found (b) (4) unacceptable due to orthographic similarity and overlapping product characteristics with the currently marketed products (b) (4) and (b) (4).

Thus, PRM Pharma submitted the proposed proprietary name, HemiClor, for review on January 17, 2024 under NDA 218647.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 17, 2024<sup>b</sup> and the prescribing information received on August 10, 2023<sup>c</sup>.

| Table 1. Relevant Product Information for HemiClor |                |
|----------------------------------------------------|----------------|
| Intended pronunciation:                            | Hem'ee klor    |
| Active ingredient:                                 | chlorthalidone |
| Indication:                                        | hypertension   |
| Dosage Form:                                       | tablets        |
| Strength:                                          | 12.5 mg        |
| Route of administration:                           | Oral           |

<sup>a</sup> Nalesnik, T. Proprietary Name Review for (b) (4) \*\* (NDA 218647). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 DEC 22. PNR ID No. 2023-1044725379.

<sup>b</sup> HemiClor Request for Proprietary name review NDA 218647. Villanova (PA): PRM Pharma, LLC; 2024 JAN 17. Available from: <\\CDSESUB1\EVSPROD\nda218647\0008\m1\us\m1-18-proprietary-names\m1-18-proprietary-name.pdf>

<sup>c</sup> HemiClor[Prescribing Information]. NDA 218647. Villanova (PA): PRM Pharma, LLC; 2023 AUG 10. Available from: <\\CDSESUB1\EVSPROD\nda218647\0001\m1\us\m1-14-labeling\m1-14-1-draft-labeling\m11413\package-outsert.docx>

| <b>Table 1. Relevant Product Information for HemiClor</b> |                                                                                                                                                                                                       |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Usual dosage and frequency:</b>                        | The initial recommended dose of Chlorthalidone is 12.5 mg once daily with food. Initiate therapy with the lowest possible dose (i.e., 12.5 mg, once daily). (b) (4)<br>(b) (4)<br>(b) (4)             |
| <b>How Supplied:</b>                                      | white to off-white, modified rectangle shaped tablets debossed with "CL" on one side and "4" on the other side, packaged as 100s count and 1000s count in HDPE bottles with child resistant closures. |
| <b>Storage:</b>                                           | Store at 20° to 25° C (68° to 77° F). [See USP Controlled Room Temperature].                                                                                                                          |

## 2 DISCUSSION

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

### 2.1 MISBRANDING ASSESSMENT

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

### 2.2 SAFETY ASSESSMENT

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

#### 2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.<sup>d</sup>

#### 2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

PRM Pharma indicated in their submission that the proposed proprietary name, HemiClor, is made of prefix "Hemi" derived from the Greek meaning "half" and in the name "HemiClor" refers to PRM's 12.5 mg dosage being half of the currently marketed higher Chlorthalidone 25 mg dosage identified by the American Heart Association and the American College of Cardiology as the highest "usual" dose of Chlorthalidone to be prescribed for the treatment of

<sup>d</sup> USAN stem search conducted on March 6, 2024.

adult hypertension<sup>e</sup>. The suffix “Clor” is phonetically derived from the prefix “Chlor” included in the product’s established generic name (i.e., Chlorthalidone).

This proprietary name is comprised of a single word that contains the letter string “OR”, which is a medical abbreviation for ‘operating room’. As the letter string ‘OR’ is located at the end of the name, we evaluated the potential risk of misinterpreting the proposed proprietary name as “[drug name similar to HemiCl] OR” and did not identify any new concerns. Additionally, we note the letters “OR” at the end of a proprietary name is common in drug nomenclature for currently marketed drug products (e.g., Caldolor, Valchlor, Ketochlor, etc.). HemiClor does not contain any other 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 February 9, 2024, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to HemiClor at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Eighty-three (n= 83) practitioners participated in DMEPA’s prescription studies for HemiClor. Four inpatient study participants misinterpreted HemiClor as (b) (4) which is a close variation to the pending name (b) (4)\*\*\*. We assess this name pair in section 2.2.7.

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<sup>f</sup> identified 104 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 lists 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.

| Table 2. Names Retrieved for Review Organized by Name Pair Similarity |                 |
|-----------------------------------------------------------------------|-----------------|
| Similarity Category                                                   | Number of Names |
| Highly similar name pair:<br>combined match percentage score ≥70%     | 2               |

<sup>e</sup> HemiClor Request for Proprietary name review NDA 218647. Villanova (PA): PRM Pharma, LLC; 2024 JAN 17. Available from: [\\CDSESUB1\EVSPROD\nda218647\0008\m1\us\m1-18-proprietary-names\m1-18-proprietary-name.pdf](#)

<sup>f</sup> POCA search conducted on March 6, 2024 in version 5.5.

|                                                                                             |    |
|---------------------------------------------------------------------------------------------|----|
| Moderately similar name pair:<br>combined match percentage score $\geq 55\%$ to $\leq 69\%$ | 87 |
| Low similarity name pair:<br>combined match percentage score $\leq 54\%$                    | 15 |

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

We determined 103 of the 104 names will not pose risk for confusion with HemiClor 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, HemiClor is dependent upon which underlying application is approved first.

(b) (4)

### **2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION**

On April 15, 2024, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

### **3 CONCLUSION**

The proposed proprietary name, HemiClor, is conditionally acceptable.

If you have further questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

### **3.1 COMMENTS TO PRM PHARMA, LLC**

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

---

<sup>¶</sup>Institute for Safe Medication Practices. Safety briefs: Advair-Advicor mix-up. ISMP Med Saf Alert Community/Ambulatory Care. 2003; 2(8): 1-2.

<sup>h</sup> Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

## 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.<sup>i</sup>

| *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                                                                                                                                                                                               | <b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>                                                                                                                                                       |
|                                                                                                                                                                                                   | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.                                                                                                   |
| Y/N                                                                                                                                                                                               | <b>Are there inert or inactive ingredients referenced in the proprietary name?</b>                                                                                                                                                                |
|                                                                                                                                                                                                   | 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                                                                                                                                                                                               | <b>Does the proprietary name include combinations of active ingredients?</b>                                                                                                                                                                      |
|                                                                                                                                                                                                   | 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                                                                                                                                                                                               | <b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>                                                                                                                                                                 |
|                                                                                                                                                                                                   | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.                                                                                                                                           |

<sup>i</sup> 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  $\geq 70\%$ .
- 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 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  $\geq 70$  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.
  - o 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<sup>j</sup>. 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.

- o 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 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-

---

<sup>j</sup> 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 $\geq$ 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?<br><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?<br><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 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 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$ ). |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1                                                                                                 | <p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Step 2                                                                                                 | <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                                                                                                        | <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> <li>• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</li> <li>• Are the lengths of the names dissimilar* when scripted?</li> <li>• *FDA considers the length of names different if the names differ by two or more letters.</li> <li>• Considering variations in scripting of some letters (such as z and f), is there a different number or</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul> |

**Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).**

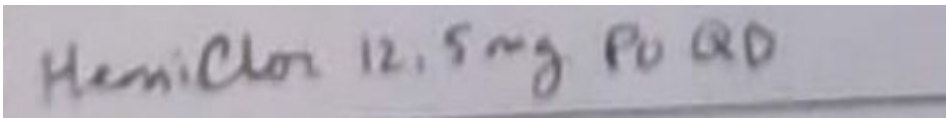
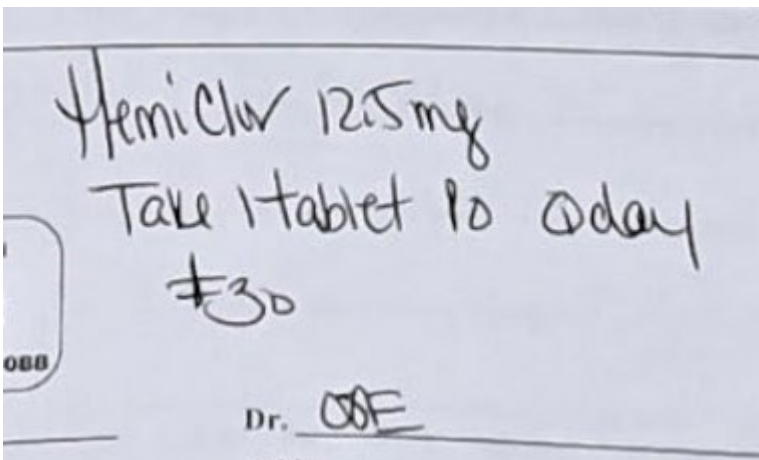
|  |                                                                                                                                                                                                                                                                                                                                                                          |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>placement of upstroke/downstroke letters present in the names?</p> <ul style="list-style-type: none"> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul> |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

**Table 6. 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. HemiClor Study (Conducted on 1/26/2024)

| Handwritten Medication Order Prescription                                                                                 | Verbal Prescription                              |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <p><u>Medication Order:</u></p>         | <p>HemiClor<br/>Take 1 tablet by mouth daily</p> |
| <p><u>Outpatient Prescription:</u></p>  |                                                  |
| <p>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</p> <p><b>HemiClor</b></p>                            |                                                  |

| FDA Prescription Simulation Responses (Aggregate Report) |           |            |       |      |       |
|----------------------------------------------------------|-----------|------------|-------|------|-------|
| Study Name: HemiClor                                     |           |            |       |      |       |
| People Received Study: 165                               |           |            |       |      |       |
| People Responded: 83                                     |           |            |       |      |       |
| Total                                                    | 22        | 18         | 23    | 20   | 83    |
| INTERPRETATION                                           | INPATIENT | OUTPATIENT | VOICE | CPOE | TOTAL |
| HEMICHLOR                                                | 0         | 0          | 11    | 0    | 11    |
| HEMICLOR                                                 | 18        | 15         | 8     | 20   | 61    |
| HEMICLORE                                                | 0         | 0          | 1     | 0    | 1     |
| HEMICLOV                                                 | 0         | 1          | 0     | 0    | 1     |
| HEMICLUR                                                 | 0         | 1          | 0     | 0    | 1     |
| HEMICLURE                                                | 0         | 0          | 1     | 0    | 1     |

|          |   |   |   |   |   |
|----------|---|---|---|---|---|
| HEMIKLOR | 0 | 0 | 2 | 0 | 2 |
| HEMLICOR | 0 | 1 | 0 | 0 | 1 |
| (b) (4)  | 4 | 0 | 0 | 0 | 4 |

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is  $\geq 70\%$ )

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Orthographic and/or phonetic differences in the names sufficient to prevent confusion<br><br>Other prevention of failure mode expected to minimize the risk of confusion between these two names.                                                                   |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | HemiClor                                                                                                                                                 | 100            | This name is the subject of this review.                                                                                                                                                                                                                            |
| 2.  | Midchlor                                                                                                                                                 | 70             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. Midchlor was a isometheptene containing product and FDA notified all manufacturers on October 12, 2017 to stop distributing isometheptene containing products. |

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

| No. | Name     | POCA Score (%) |
|-----|----------|----------------|
| 1.  | Habitrol | 60             |
| 2.  | Hemmorex | 56             |

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: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | Raniclor                                                                                                                                                 | 68             | Orthographically, the starting letters 'R' vs. 'H' and prefixes 'Ran' vs. 'Hem' provide some difference.<br>Phonetically the first syllables 'ran' vs 'hem' are different.       |

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                          |                | <p>Additionally, Raniclor is the tradename of deactivated chewable oral tablet cefaclor with no cefaclor chewable tablets currently marketed. Cefaclor is available in multiple dosage forms: oral capsule (250 mg, 500 mg), oral tablet extended release (500 mg), and for oral suspension (125 mg/5 mL, 250 mg/5 mL, 375 mg/5 mL when mixed) so a prescription for Cefaclor would need to specify dosage form. Although there is numerical similarity in strength (125 mg/5 mL of for oral suspension dosage form vs. 12.5 mg/mL), the name pair differ in frequency (once daily vs/ every 8-12 hours). Thus, in this specific case, the risk of name confusion between this name pair is minimized</p> |
| 2.  | Cefaclor                                                                                                                                                 | 67             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.  | (b) (4)                                                                                                                                                  | 65             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4.  | (b) (4)                                                                                                                                                  | 63             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 5.  | (b) (4) **                                                                                                                                               | 64             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 6.  | Hi-Cor                                                                                                                                                   | 62             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 7.  | Hemril-30                                                                                                                                                | 61             | Orthographically, the name pair differs in length (8 letters vs. 6 letters) and the suffix (-clor vs. -ril) provide sufficient differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |



| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names                                                                                                                                                                                                                                                                                                                                                |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                          |                | <p>This name pair has sufficient phonetic differences.</p> <p>Although both products are single strength (30 mg vs. 12.5 mg), where the strength may be omitted on a prescription, they differ in dosage form (suppository vs. tablets), route of administration (rectal vs. oral), and frequency of administration (twice daily or three times daily vs. once daily). Thus, in this specific case, the risk of name confusion between this name pair is minimized.</p>                                                         |
| 8.  | Hemril                                                                                                                                                   | 61             | <p>Orthographically, the name pair differs in length (8 letters vs. 6 letters) and the suffix (-clor vs. -ril) provide sufficient differences. '</p> <p>This name pair has sufficient phonetic differences.</p> <p>Although both products are single strength (30 mg vs. 12.5 mg), where the strength may be omitted on a prescription, they differ in dosage form (suppository vs. tablets), route of administration (rectal vs. oral), and frequency of administration (twice daily or three times daily vs. once daily).</p> |

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                          |                | Thus, in this specific case, the risk of name confusion between this name pair is minimized.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 9.  | Hemlibra                                                                                                                                                 | 61             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 10. | Tri-Chlor                                                                                                                                                | 60             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 11. | Emcin Clear                                                                                                                                              | 60             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 12. | Hibiclens                                                                                                                                                | 60             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 13. | Hemofil                                                                                                                                                  | 60             | <p>Orthographically, Hemiclor contains the dotted letter 'i' in the infix while Hemofil contains the rounded letter 'o' in the infix. Additionally, the suffix of the name pair (-clor vs, -fil) provide sufficient difference.</p> <p>This name pair has sufficient phonetic differences.</p> <p>Although both products are single strength (1 U vs. 12.5 mg), where the strength may be omitted on a prescription, they differ in dosage form (powder for solution vs. tablet), route of administration (intravenous vs. oral), and frequency of administration (as needed vs. daily).</p> |

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                          |                | Thus, in this specific case, the risk of name confusion between this name pair is minimized.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 14. | Gemcor                                                                                                                                                   | 60             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 15. | Micronor                                                                                                                                                 | 59             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 16. | Famciclovir                                                                                                                                              | 59             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 17. | Hongo Killer                                                                                                                                             | 58             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 18. | Maxichlor                                                                                                                                                | 58             | <p>Orthographically, the prefixes differ ('Max' vs. 'Hem'). Additionally, Maxichlor contains an additional upstroke letter 'h' in the suffix not seen in Hemiclor which provides some differences.</p> <p>Phonetically, the first syllable of this name pair sounds different 'max' vs. 'hem.'</p> <p>Additionally, Maxichlor is a root name for a line of over the counter cough and cold products (e.g. Maxichlor PEH, Maxichlor PEH DM, Maxichlor PSE, and Maxichlor PSE DM). We note that the root name alone, Maxichlor, is not marketed product, therefore, when prescribing products in the Maxichlor product line, the prescription will need to specify the modifier for the specific Maxichlor product. The modifiers provide additional orthographic and phonetic differences.</p> |

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                          |                | Furthermore, there is no direct overlap in strength (4 mg/10 mg, 4 mg/18 mg/10 mg, 4 mg/60 mg, or 4 mg/20 mg/60 mg vs. 12.5 mg) or frequency (as needed vs. daily).<br><br>Thus, in this specific case, the risk of name confusion between this name pair is minimized.                                                                                                                                                                                                                                                                                                                                                                                                    |
| 19. | Hemorid                                                                                                                                                  | 58             | Orthographically, the suffix of the name pair(' -rid' vs. ' -clor') provides some difference.<br><br>This name pair has sufficient phonetic differences.<br><br>Although both products are single strength (12.5 mg vs. 0.25%/(b)(4)%) where a prescription order may not include the strength, the name pair differ in route of administration (rectal vs. oral) and frequency (up to 4 times daily as needed vs. once daily). Additionally, the dosage form differ (tablet vs. cream, lotion and suppositories) and an order for Hemorid would need to specify dosage form. Thus, in this specific case, the risk of name confusion between this name pair is minimized. |
| 20. | Hectorol                                                                                                                                                 | 58             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 21. | Humulin R                                                                                                                                                | 58             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 22. | Penciclovir                                                                                                                                              | 57             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

| No. | Proposed name: HemiClor<br>Established name: chlorthalidone<br>Dosage form: tablets<br>Strength(s): 12.5 mg<br>Usual dose: 1 tablet by mouth once daily. | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 23. | Micrell                                                                                                                                                  | 57             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 24. | (b) (4)                                                                                                                                                  | 57             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 25. | Hemox A                                                                                                                                                  | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 26. | Hemorrodil                                                                                                                                               | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 27. | Hemax                                                                                                                                                    | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 28. | Micort-Hc                                                                                                                                                | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 29. | Hecoria                                                                                                                                                  | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 30. | Cefaclor Er                                                                                                                                              | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |
| 31. | (b) (4) ***                                                                                                                                              | 55             | This name pair has sufficient orthographic and phonetic differences.                                                                                                             |

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

| No. | Name             | POCA Score (%) |
|-----|------------------|----------------|
| 1.  | Aemcolo          | 54             |
| 2.  | Chromic Chloride | 54             |
| 3.  | Ethimil Mr       | 54             |
| 4.  | (b) (4) ***      | 54             |
| 5.  | Chromic Fluoride | 52             |
| 6.  | Hemorid Cream    | 51             |
| 7.  | Miochol          | 49             |
| 8.  | Ferric Chloride  | 48             |

| No. | Name              | POCA Score (%) |
|-----|-------------------|----------------|
| 9.  | Maxichlor Peh     | 48             |
| 10. | Cesium Chloride   | 47             |
| 11. | Lithium Chloride  | 46             |
| 12. | Maxichlor Pse     | 46             |
| 13. | Miochol-E         | 46             |
| 14. | Mio-Rel           | 45             |
| 15. | Mercuric Chloride | 42             |

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.  | Indiclor   | 68             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                                                                                                                                  |
| 2.  | Epiklor    | 68             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                                           |
| 3.  | Tenchlor   | 66             | International product marketed in South Africa, UK, Hong Kong, and formerly marketed in Ireland.                                                                                                                                                                                      |
| 4.  | Biclora    | 63             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                                                                                                                                  |
| 5.  | Emcor      | 62             | International product currently marketed in Ireland and Netherlands.                                                                                                                                                                                                                  |
| 6.  | Ketochlor  | 62             | This is a veterinary drug product.                                                                                                                                                                                                                                                    |
| 7.  | Hemochron  | 62             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                                           |
| 8.  | Pediachlor | 61             | International product formerly marketed in Phillippines.                                                                                                                                                                                                                              |
| 9.  | Haemaccel  | 61             | Currently market: India, Turkey, Indonesia, Portugal, and Thailand.<br>Formerly marketed: Australia, New Zealand, Mexico, Belgium, Czech Republic, Hong Kong, Israel, Malaysia, Switzerland, Malaysia, Argentina, Austria, Germany, Norway, Singapore, Finland, Sweden, France, South |

| No. | Name        | POCA Score (%) | Failure preventions                                                                                                                                                   |
|-----|-------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |             |                | Africa, Denmark, Germany, Ireland, Netherlands, Brazil, and Chile.                                                                                                    |
| 10. | Hycoclear   | 60             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                           |
| 11. | Econochlor  | 60             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                  |
| 12. | Dm-Pe-Chlor | 60             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                  |
| 13. | De-Chlor G  | 60             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                  |
| 14. | Amilomer    | 60             | Active ingredient for Spherex, an international product formerly marketed in Germany.                                                                                 |
| 15. | (b) (4) *** | 58             | Proposed proprietary name for IND 104034 found unacceptable by DMEPA (OSE# 2016-9906028 dated 12/16/2016). NDA 210910 is approved under the proprietary name Aemcolo. |
| 16. | Helicosol   | 58             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                           |
| 17. | Biclora-D   | 58             | Name identified in RxNorm database. Product deactivated and no generic equivalents are available.                                                                     |
| 18. | Dicloran    | 57             | International product marketed in Hong Kong, Mexico, and Russia.                                                                                                      |
| 19. | De-Chlor Mr | 57             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                  |
| 20. | Pseuclor    | 56             | Name identified in RxNorm database. Root name for 'Pseuclor-SR', which is deactivated, and no generic equivalents are available.                                      |
| 21. | Ocu-Chlor   | 56             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.                                                                  |
| 22. | Microderm   | 56             | Brand discontinued with no generic equivalents available. ANDA 072255/072295 withdrawn FR effective 10/22/2021.                                                       |
| 23. | Hydraclear  | 56             | Product is not a drug. It is a modifier for contact lenses.                                                                                                           |

| No. | Name        | POCA Score (%) | Failure preventions                                                                                         |
|-----|-------------|----------------|-------------------------------------------------------------------------------------------------------------|
| 24. | Emcor Ls    | 56             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 25. | De-Chlor Hc | 56             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.        |
| 26. | De-Chlor Dm | 56             | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.        |

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion<sup>k</sup>.

| No. | Name         | POCA Score (%) |
|-----|--------------|----------------|
| 1.  | Acneclir     | 61             |
| 2.  | Rhinocort    | 60             |
| 3.  | Aldoclor     | 58             |
| 4.  | Aldoclor-150 | 58             |
| 5.  | Aldoclor-250 | 58             |
| 6.  | Nicolar      | 58             |
| 7.  | Pamelor      | 58             |
| 8.  | Simcor       | 58             |
| 9.  | Dymelor      | 56             |
| 10. | Emetrol      | 56             |
| 11. | Epicort      | 56             |
| 12. | Epiflur      | 56             |
| 13. | Inocor       | 56             |
| 14. | Kaochlor     | 56             |
| 15. | M-Clear      | 56             |
| 16. | Medicort     | 56             |
| 17. | Omacor       | 56             |
| 18. | Ony-Clear    | 56             |

<sup>k</sup> Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016



| No. | Name          | POCA Score (%) |
|-----|---------------|----------------|
| 19. | Theoclear     | 56             |
| 20. | Theoclear-100 | 56             |
| 21. | Theoclear-200 | 56             |
| 22. | Theoclear-80  | 56             |
| 23. | Zemplar       | 56             |
| 24. | Ceberclon     | 55             |
| 25. | Complera      | 55             |
| 26. | (b) (4) **    | 55             |
| 27. | Fibricor      | 55             |

-----  
**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/  
-----

SALI MAHMOUD  
04/16/2024 03:41:05 PM

NICOLE F IVERSON  
04/16/2024 03:44:18 PM

HINA S MEHTA  
04/16/2024 04:10:01 PM

---

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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

---

|                                                           |                                            |
|-----------------------------------------------------------|--------------------------------------------|
| Date of This Review:                                      | July 8, 2024                               |
| Application Type and Number:                              | NDA 218647                                 |
| Product Name, Dosage Form, and Strength:                  | Hemiclor (chlorthalidone) tablets, 12.5 mg |
| Product Type:                                             | Single Ingredient Product                  |
| Rx or OTC:                                                | Prescription (Rx)                          |
| Applicant/Sponsor Name:                                   | PRM Pharma, LLC (PRM Pharma)               |
| PNR ID #:                                                 | 2024-1044725572-1                          |
| DMEPA 2 Team Leader:                                      | Nicole Iverson, PharmD, BCPS               |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD                         |

---

## 1 INTRODUCTION

This memorandum is to amend the previous decision regarding the acceptability of the proposed proprietary name, Hemiclor, which was found conditionally acceptable under NDA 218647 on April 16, 2024.<sup>a</sup> We note that a conflict exists with another similar pending proposed proprietary name that is currently under review.

## 2 DISCUSSION

### 2.1 SAFETY ASSESSMENT

DMEPA 2 had previously reviewed the proposed proprietary name, Hemiclor, under NDA 218647 and issued a **CONDITIONALLY ACCEPTABLE** letter for this name. Since that time, we have identified a conflict with another pending proposed proprietary name that is currently under review. The proposed proprietary name, Hemiclor, could result in medication errors due to confusion with (b) (4) \*\*. Our evaluation of this name pair has altered our previous conclusion regarding the acceptability of the proposed proprietary name. The rationale for the risk of confusion is described below.

(b) (4)

<sup>a</sup> Mahmoud, S. Proprietary Name Review for HemiClor (NDA 218647). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APR 16. PNR ID No. 2024-1044725572.

## 2.2 COMMUNICATION OF DMEPA'S DETERMINATION

On July 8, 2024, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

## 3 CONCLUSION

The proposed proprietary name is not acceptable from a safety perspective. The proposed proprietary name, Hemiclor, is vulnerable to name confusion with (b) (4) \*\*.

### 3.1 COMMENTS TO PRM PHARMA, LLC

Your proposed proprietary name, Hemiclor, was found conditionally acceptable on April 16, 2024. Since that time, we have determined that your proposed proprietary name, Hemiclor, could result in medication errors due to confusion with another product that is currently under review. Therefore, the ultimate acceptability of your proposed proprietary name, Hemiclor, is dependent upon which underlying application is approved first. If another product is approved

---

<sup>b</sup> Institute for Safe Medication Practices. Safety briefs: Advair-Advicor mix-up. ISMP Med Saf Alert Community/Ambulatory Care. 2003; 2(8): 1-2.

<sup>c</sup> Schiff GD, Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

prior to your product, with a proprietary name that would be confused with your proposed proprietary name, Hemiclor, you will be requested to submit another proprietary name.

-----  
**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/  
-----

NICOLE F IVERSON  
07/08/2024 03:37:51 PM

HINA S MEHTA  
07/08/2024 03:58:27 PM

---

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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

---

|                                                                  |                                          |
|------------------------------------------------------------------|------------------------------------------|
| <b>Date of This Review:</b>                                      | December 22, 2023                        |
| <b>Application Type and Number:</b>                              | NDA 218647                               |
| <b>Product Name and Strength:</b>                                | (b) (4) (chlorthalidone) Tablet, 12.5 mg |
| <b>Product Type:</b>                                             | Single Ingredient Product                |
| <b>Rx or OTC:</b>                                                | Prescription (Rx)                        |
| <b>Applicant/Sponsor Name:</b>                                   | PRM Pharma, LLC (PRM Pharma)             |
| <b>PNR ID #:</b>                                                 | 2023-1044725379                          |
| <b>DMEPA 2 Safety Evaluator:</b>                                 | Tayler Nalesnik, PharmD, MS              |
| <b>DMEPA 2 Team Leader:</b>                                      | Nicole Iverson, PharmD, BCPS             |
| <b>(acting)</b>                                                  |                                          |
| <b>DMEPA 2 Associate Director for Nomenclature and Labeling:</b> | Hina Mehta, PharmD                       |
| <b>(acting)</b>                                                  |                                          |

---



-----  
**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/  
-----

TAYLER E NALESNIK  
12/26/2023 12:26:43 PM

NICOLE F IVERSON  
12/26/2023 07:55:16 PM

HINA S MEHTA  
12/27/2023 09:09:00 AM