# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 219141Orig1s000

# 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: | January 14, 2025 |
| Application Type and Number: | NDA 219141 |
| Product Name, Dosage Form, and Strength: | Inzirqo (hydrochlorothiazide) for oral suspension, 10 mg/mL |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Novitium Pharma LLC (Novitium) |
| PNR ID #: | 2024-1044725979-1 |
| DMEPA 2 Safety Evaluator: | Jody Kundreskas, PharmD |
| DMEPA 2 Team Leader: | Nicole Iverson, PharmD, BCPS |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD |



Reference ID: 5511101

# 1 INTRODUCTION

This memorandum is initiated by DMEPA 2 to reassess the proposed proprietary name, Inzirqo, to evaluate the change in strength. Previously, the proposed proprietary name, Inzirqo, was found conditionally acceptable under NDA 219141 as (b) (4) on November 26, 2024.[a] However, during the review cycle, the Division of Cardiology and Nephrology (DCN) determined that the strength should be expressed as 10 mg/mL.

# 2 DISCUSSION

## 2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Inzirqo, we evaluated the previously identified names taking into account the change in strength from (b) (4) to 10 mg/mL. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Inzirqo.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 23, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Inzirqo.

# 3 CONCLUSION

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

[a] Kundreskas, J. Proprietary Name Review for Inzirqo (NDA 219141). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 NOV 26. PNR ID No. 2024-1044725979.

## 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.

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**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.**

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/s/

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JODY K KUNDRESKAS
01/14/2025 09:39:50 AM

NICOLE F IVERSON
01/14/2025 09:57:32 AM

HINA S MEHTA
01/14/2025 12:44:59 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)

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| | |
|---|---|
| Date of This Review: | November 26, 2024 |
| Application Type and Number: | NDA 219141 |
| Product Name, Dosage Form, and Strength: | Inzirqo (hydrochlorothiazide) for oral suspension, (b) (4) (b) (4) |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Novitium Pharma LLC (Novitium) |
| PNR ID #: | 2024-1044725979 |
| DMEPA 2 Safety Evaluator: | Jody Kundreskas, PharmD |
| DMEPA 2 Team Leader: | Nicole Iverson, PharmD, BCPS |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD |



Reference ID: 5486245

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Reference ID: 5486245

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Inzirqo, 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. Novitium submitted an external name study, conducted by [redacted] for this proposed proprietary name.

## 1.1 REGULATORY HISTORY

Novitium previously submitted the proposed proprietary name, [redacted] ** under NDA 219141 on March 28, 2024. However, on August 15, 2024, we found the name, [redacted]*** unacceptable due to orthographic similarities and overlapping product characteristics with the proprietary name, [redacted]

Thus, Novitium submitted the proposed proprietary name, Inzirqo, for review on September 11, 2024 under NDA 219141.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission[c] and the prescribing information[d] received on September 11, 2024.

| Table 1. Relevant Product Information for Inzirqo | |
|---|---|
| **Intended pronunciation:** | in-ZURR-ko |
| **Active ingredient:** | hydrochlorothiazide |
| **Indication:** | • [redacted]edema associated with congestive heart failure, hepatic cirrhosis, [redacted]enal dysfunction such as nephrotic syndrome, [redacted]<br>• [redacted]of hypertension [redacted]or to enhance the effectiv [redacted]ve drugs [redacted] |
| **Dosage Form:** | for oral suspension |
| **Strength:** | [redacted] |

[a] Request for Proprietary Name Review (NDA 219141). [redacted] 2024 SEP 11. Available from: \\CDSESUB1\EVSPROD\nda219141\0008\m1\us\118-proprietary-name-review-report-inzirqo.pdf.

[b] Kundreskas, J. Proprietary Name Review for [redacted]*** (NDA 219141). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 15. PNR ID No. 2024-1044725798.

[c] Proprietary Name Request for Inzirqo (NDA 219141). East Windsor (NJ): Novitium Pharma LLC; 2024 SEP 11. Available from: \\CDSESUB1\EVSPROD\nda219141\0008\m1\us\118-proprietary-name-request-inzirqo.pdf.

[d] Proposed Prescribing Information for Inzirqo. East Windsor (NJ): Novitium Pharma LLC; 2024 SEP 11. Available from: \\CDSESUB1\EVSPROD\nda219141\0008\m1\us\11413-draft-package-insert-pdf.pdf.

| Table 1. Relevant Product Information for Inzirqo | |
|---|---|
| **Route of administration:** | Oral |
| **Dose and frequency:** | • [redacted] Hypertension<br>[redacted] initial dose in adults is 25 mg daily given as a single dose. The dose may be increased to 50 mg daily, given as a single or two divided doses. [redacted]<br>• Treatment of Edema in Adults<br>[redacted] adult dosage is 25 mg to 100 mg daily as a single or divided dose. [redacted] intermittent therapy, i.e., administration on alternate days or on 3 to 5 days each week. [redacted] electrolyte imbalance are less likely to occur.<br>• [redacted] Hypertension)<br>[redacted] pediatric dosage is 1 to 2 mg/kg per day in single or two divided doses, not to exceed 37.5 mg per day in [redacted] up to 2 years of age or 100 mg per day in children 2 to 12 years of age. In [redacted] less than 6 months of age, doses up to 3 mg/kg per day in two divided doses may be required. |
| **How Supplied:** | As an off-white to light-brown colored powder for oral suspension in one strength containing 800 mg of hydrochlorothiazide, USP in a HDPE bottle.<br>When reconstituted as directed, INZIRQO forms an off-white to light brown colored suspension with caramel, peppermint flavor. The total volume of the suspension is 80 mL containing [redacted] mg of hydrochlorothiazide, USP per [redacted] mL (70954-522-10). |
| **Storage:** | Dry Powder and Suspension: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Do not freeze.<br>Keep this and all medication out of the reach of children.<br>Discard any unused suspension 30 days after reconstitution. |
| **Listed Drug:** | Hydrodiuril (hydrochlorothiazide) NDA 011835 |

## 2 DISCUSSION

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

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Inzirqo 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 Inzirqo. The Division of Cardiology and Nephrology (DCN) did not comment on the findings of OPDP's assessment for Inzirqo.

## 2.2 SAFETY ASSESSMENT

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

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

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

### 2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Novitium did not provide a derivation or intended meaning for the proposed proprietary name, Inzirqo, in their submission. This proprietary name is comprised of a single word that contains the letter strings "IN" and "IR", which are medical abbreviations for the route of administration "intranasal" and the modifier "immediate release", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter string "IR" is embedded within the infix of the proposed proprietary name and is unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription and lead to confusion.

Since the letter string "IN" is located at the beginning of the name, we evaluated the potential risk of misinterpreting the proprietary name as "IN [drug name similar to ZIRQO]"[f] and identified the name "Zingo". We considered the risk if Inzirqo were to be interpreted as "IN Zingo". We note that Zingo is a combination product and is only available as a device for intradermal use. Zingo is applied as a single dose by a healthcare provider 1 to 3 minutes prior to venipuncture or intravenous cannulation procedure. Zingo is a ready-to-use, sterile, single-use, disposable, needle-free delivery system and consists of a drug reservoir cassette filled with 0.5 mg lidocaine hydrochloride monohydrate as a powder, a pressurized helium gas cylinder, and a safety interlock. The safety interlock prevents inadvertent actuation of the device. Once ZINGO is pressed against the skin, the interlock is released, allowing the button to be depressed to actuate the device. A sound similar to that of a popping balloon is emitted at the time Zingo is actuated. Due to the size of the device and the tasks needed to be performed to actuate it, intranasal administration is not possible. We further evaluated this name pair (See Section 2.2.4 and Appendix E) for risk of confusion and find it unlikely that Inzirqo would be confused as intranasal Zingo. Thus, in this case we do not object to the inclusion of these letter strings.

[e] USAN stem search conducted on September 19, 2024.

[f] POCA search conducted on September 19, 2024 in version 5.9.

Inzirqo does not contain any other components (i.e., frequency, dosage form, etc.) that can contribute to medication error.

### 2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On October 16, 2024, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Inzirqo at the initial phase of the review.

### 2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-two (82) practitioners participated in DMEPA's prescription simulation studies for Inzirqo.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name Inqovi. However, the participant entered an incorrect sequence of letters, 'Inq' when searching for the study name. As a result, the CPOE generated picklist did not contain Inzirqo as a choice. The participant proceeded to incorrectly select Inqovi as their response after 14 seconds in order to proceed with the FDA prescription stimulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Despite this, we further evaluated Inzirqo vs. Inqovi and determined that this name pair has sufficient orthographic and phonetic differences.

Orthographically, the dotted letter 'i' and downstroke letter 'q' are located in different positions within each name pair (4$^{th}$ vs. last position and 6$^{th}$ vs. 3$^{rd}$ position, respectively).

Phonetically, the second (ZURR vs. koe) and third (ko vs. vee) syllables sound different.

We considered whether additional product characteristics would help differentiate the products during an electronic prescribing scenario. We note the dosage form (for oral suspension vs. tablet) and frequency (daily continuously vs. daily for 5 days of a 28 day cycle) differ between the two products. Thus, if included on a prescription, the risk of name confusion between the name pair is minimized in this case (see Appendix E).

Additionally, 9 participants in the inpatient written study misinterpreted the proposed proprietary name as "Inzingo", which is a close variation of the marketed product "Zingo". We further evaluated this name pair for risk of medication errors.

Orthographically, the name pair differ in length (7 letters vs. 5 letters) giving the names different shapes when scripted. Additionally, the name pairs begin with differently shaped letters ('I' vs. 'Z') which provides some orthographic difference.

Phonetically, the onset of the first syllables (In vs. Zinn) sound different and Inzirqo contains an extra syllable compared to Zingo.

The name pair differ in strength (b) (4) vs. 0.5 mg), dosage form (for oral suspension vs. powder intradermal injection system), route (oral vs. intradermal), dose (25 mg, 50 mg, 100 mg, 1 mg/kg, 1.5 mg/kg, or 2 mg/kg vs. 0.5 mg), and frequency (one or twice daily vs. once prior to venipuncture or intravenous cannulation).

When all of the aforementioned factors are considered in totality, we find the risk of name confusion between the name pair is adequately minimized in this case (see Appendix E).

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[g] identified 24 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

### 2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA searches, FDA Prescription Simulation Study, and (b) (4) external study. 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% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 24 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 7 |

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

Our analysis of the 32 names contained in Table 2 determined none of the names will pose a risk for confusion with Inzirqo as described in Appendices C through H.

### 2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On November 26, 2024, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

## 3 CONCLUSION

The proposed proprietary name, Inzirqo, is conditionally acceptable.

### 3.1 COMMENTS TO NOVITIUM PHARMA LLC

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

[g] POCA search conducted on September 19, 2024 in version 5.9.

If any of the proposed product characteristics as stated in your submission, received on September 11, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

## 4 REFERENCES

*1. United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

*2. Phonetic and Orthographic Computer Analysis (POCA)*

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

*Drugs@FDA*

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

*RxNorm*

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

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

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

*Purple Book*

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

*Division of Medication Errors Prevention and Analysis pending proprietary name requests*

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

# 5 APPENDICES

## APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[h]

| *Table 3. Prescreening Checklist for Proposed Proprietary Name<br>Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance. | |
|---|---|
| Y/N | Is the proposed name obviously similar in spelling and pronunciation to other names? |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| Y/N | Are there inert or inactive ingredients referenced in the proprietary name? |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| Y/N | Does the proprietary name include combinations of active ingredients? |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| Y/N | Is there a United States Adopted Name (USAN) stem in the proprietary name? |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |

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



Reference ID: 5486245

| *Table 3. Prescreening Checklist for Proposed Proprietary Name<br>Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance. | |
|---|---|
| Y/N | Is this proprietary name used for another product that does not share at least one common active ingredient? |
| | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name. |
| Y/N | Is this a proprietary name of a discontinued product? |
| | Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients. |

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[i]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information 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-

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

concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary Safety Evaluator assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

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



Reference ID: 5486245

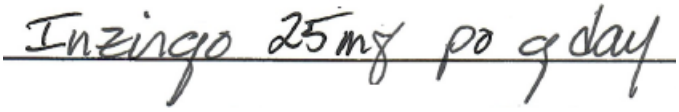
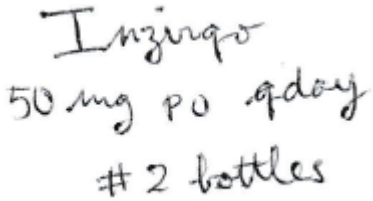
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.<br>For single strength products, also consider circumstances where the strength may not be expressed.<br>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.<br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br>• 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.<br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br>• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>• *FDA considers the length of names different if the names differ by two or more letters.<br>• Considering variations in scripting of some letters (such as z and f), is there a different number or</td><td>Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

| Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).** | | |
|---|---|---|
| | placement of upstroke/downstroke letters present in the names?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | |

| Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤54%).** |
|---|
| Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist. |

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Inzirqo Study (Conducted on 9/20/2024)

| Handwritten Medication Order Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Inzirqo<br>50 mg by mouth once daily<br>Dispense 2 bottles |
| Outpatient Prescription:<br>  <br> | |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font) | |
| **Inzirqo** | |

| FDA Prescription Simulation Responses (Aggregate Report) | | | | | |
|---|---|---|---|---|---|
| Study Name: Inzirqo<br>People Received Study: 187<br>People Responded: 82 | | | | | |
| Total | 22 | 21 | 16 | 23 | 82 |
| INTERPRETATION | INPATIENT | OUTPATIENT | VOICE | CPOE | TOTAL |
| ENZELGO | 0 | 0 | 1 | 0 | 1 |
| ENZERCO | 0 | 0 | 1 | 0 | 1 |
| ENZERKO | 0 | 0 | 1 | 0 | 1 |
| ENZIRCO | 0 | 0 | 1 | 0 | 1 |
| ENZURKO | 0 | 0 | 1 | 0 | 1 |
| INQOVI | 0 | 0 | 0 | 1 | 1 |
| INXERCO | 0 | 0 | 1 | 0 | 1 |
| INZERCO | 0 | 0 | 5 | 0 | 5 |
| INZERKGO | 0 | 0 | 1 | 0 | 1 |
| INZERKO | 0 | 0 | 2 | 0 | 2 |
| INZINGO | 9 | 0 | 0 | 0 | 9 |

| | | | | | |
|---|---|---|---|---|---|
| INZINGQO | 1 | 0 | 0 | 0 | 1 |
| INZINQO | 5 | 2 | 0 | 0 | 7 |
| INZIRCO | 0 | 0 | 1 | 0 | 1 |
| INZIRGO | 1 | 7 | 0 | 0 | 8 |
| INZIRQO | 6 | 12 | 0 | 22 | 40 |
| INZURCO | 0 | 0 | 1 | 0 | 1 |



Reference ID: 5486245

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

| No. | **Proposed name:** Inzirqo<br>**Pronunciation:** in-ZURR-ko<br>**Established name:** hydrochlorothiazide<br>**Dosage form:** for oral suspension<br>**Strength(s):** (b) (4)<br>**Dosage:** Adults: 25 mg, 50 mg, or 100 mg, by mouth daily as a single or divided dose. Pediatrics: 1 mg/kg, 1.5 mg/kg, or 2 mg/kg per day orally once or twice daily. Maximum dose 37.5 mg once daily in infants up to 2 years of age or 100 mg in children 2 to 12 years of age. | **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. | Inzirqo | 100 | This name is the subject of this review. |

**APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose**

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | N/A | |

**APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose**

| No. | **Proposed name:** Inzirqo<br>**Pronunciation:** in-ZURR-ko<br>**Established name:** hydrochlorothiazide<br>**Dosage form:** for oral suspension<br>**Strength(s):** (b) (4)<br>**Dosage:** Adults: 25 mg, 50 mg, or 100 mg, by mouth daily as a single or divided dose. Pediatrics: 1 mg/kg, 1.5 mg/kg, or 2 mg/kg per day orally once or twice daily. Maximum dose 37.5 mg once daily in infants up to 2 years of age or 100 mg in children 2 to 12 years of age. | **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. | (b) (4)*** | 58 | Orthographically, this name pair begin with differently shaped letters ('I' vs. (b) (4). (b) (4) contains the (b) (4) (b) (4) which is not present in Inzirqo, providing some visual difference. Additionally, Inzirqo contains the optional downstroke letter 'z', and if scripted with the downstroke, provides additional visual difference to the name pairs.<br><br>Phonetically, the second syllables ('zurr' vs. (b) (4) sound different.<br><br>Although both products are single strength (10 mg/mL vs. (b) (4) where the strength may be omitted on a prescription, they differ in dosage form (for oral suspension vs. (b) (4). Thus, if included on a prescription, the risk of name confusion between the name pair is minimized in this case. |
| 2. | Inzo | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 3. | Adcirca | 56 | This name pair has sufficient orthographic differences. |

| No. | **Proposed name:** Inzirqo<br>**Pronunciation:** in-ZURR-ko<br>**Established name:** hydrochlorothiazide<br>**Dosage form:** for oral suspension<br>**Strength(s):** (b) (4)<br>**Dosage:** Adults: 25 mg, 50 mg, or 100 mg, by mouth daily as a single or divided dose. Pediatrics: 1 mg/kg, 1.5 mg/kg, or 2 mg/kg per day orally once or twice daily. Maximum dose 37.5 mg once daily in infants up to 2 years of age or 100 mg in children 2 to 12 years of age. | **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** |
|---|---|---|---|
| | | | Phonetically, the first syllable ('In' vs. 'Add') and the ending of the third syllables ('ko' vs. 'cah') sound different.<br><br>Although both products are single strength (10 mg/mL vs. 20 mg) where the strength may be omitted on a prescription, they differ in dosage form (for oral suspension vs. tablet). Thus, if included on a prescription, the risk of name confusion between the name pair is minimized in this case. |
| 4. | Intron A | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 5. | Ixiaro | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Iqirvo | 55 | Orthographically, the downstroke letter 'q' is located in different positions within the name pairs (6th vs. 2nd position). Additionally, Inzirqo contains the rounded letter 'n' in the 2nd position and optional downstroke letter 'z' in the 4th position, which if scripted with the downstroke, |

| No. | **Proposed name:** Inzirqo<br>**Pronunciation:** in-ZURR-ko<br>**Established name:** hydrochlorothiazide<br>**Dosage form:** for oral suspension<br>**Strength(s):** (b) (4)<br>**Dosage:** Adults: 25 mg, 50 mg, or 100 mg, by mouth daily as a single or divided dose. Pediatrics: 1 mg/kg, 1.5 mg/kg, or 2 mg/kg per day orally once or twice daily. Maximum dose 37.5 mg once daily in infants up to 2 years of age or 100 mg in children 2 to 12 years of age. | **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** |
|---|---|---|---|
| | | | provides additional visual difference to the name pairs.<br><br>This name pair has sufficient phonetic differences.<br><br>Although both products are single strength (10 mg/mL vs. 80 mg) where the strength may be omitted on a prescription, they differ in dosage form (for oral suspension vs. tablet). Thus, if included on a prescription, the risk of name confusion between the name pair is minimized in this case. |
| 7. | (b) (4) ** | 55 | Orthographically, these name pairs begin with differently shaped letters ('l' vs. (b) (4). The dotted letter (b) (4) is located in different positions within the name pair (b) (4) position). Both name pairs contain the optional (b) (4) letter (b) (4) in different positions (b) (4) and if scripted without the (b) (4) this provides additional visual difference to the name pairs. |

| No. | **Proposed name:** Inzirqo<br>**Pronunciation:** in-ZURR-ko<br>**Established name:** hydrochlorothiazide<br>**Dosage form:** for oral suspension<br>**Strength(s):** (b) (4)<br>**Dosage:** Adults: 25 mg, 50 mg, or 100 mg, by mouth daily as a single or divided dose. Pediatrics: 1 mg/kg, 1.5 mg/kg, or 2 mg/kg per day orally once or twice daily. Maximum dose 37.5 mg once daily in infants up to 2 years of age or 100 mg in children 2 to 12 years of age. | **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** |
|---|---|---|---|
| | | | This name pair has sufficient phonetic differences.<br><br>This name pair differ in dosage form (for oral suspension vs. (b) (4), route of administration (oral vs. (b) (4) and frequency (daily continuously vs. (b) (4) (b) (4). Additionally, (b) (4) *** is (b) (4) cause (b) (4) drugs administered by healthcare providers typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the difference in dosage form, route of administration, and frequency is minimized. |
| 8. | Inqovi | 50 | See FMEA in Section 2.2.4. |
| 9. | Zingo | 44 | See FMEA in Section 2.2.2 and 2.2.4. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Inspra | 48 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 2. | Entresto | 46 |
| 3. | Isoniazid | 41 |
| 4. | Zyrtec | 37 |
| 5. | Zocor | 36 |
| 6. | Invega Sustenna | 22 |

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. | Indigo | 64 | Product is not a drug. It is homeopathic product and a dye. |
| 2. | Benziq | 60 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 3. | (b) (4) *** | 60 | (b) (4) |
| 4. | Imferon | 56 | International drug product currently marketed in India and formerly marketed in Australia, Belgium, Canada, Netherlands, the United Kingdom, Spain, Mexico, and South Africa. |
| 5. | Indiclor | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 6. | Introl | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 7. | (b) (4) ** | 56 | (b) (4) |

| No. | Name | POCA Score (%) | Failure preventions (b) (4) |
|---|---|---|---|
| | | | |
| 8. | (b) (4)*** | 56 | Proposed proprietary name for IND 132214 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# 2020-43446894). Subsequently, the product was approved with the proprietary name Rivfloza under NDA 215842. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Ninlaro | 60 |
| 2. | Rinvoq Os*** | 58 |
| 3. | (b) (4)*** | 57 |
| 4. | Azmiro*** | 56 |
| 5. | (b) (4)*** | 56 |
| 6. | (b) (4)*** | 56 |
| 7. | Rinvoq | 56 |
| 8. | Univert | 56 |

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

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 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: | August 15, 2024 |
| Application Type and Number: | NDA 219141 |
| Product Name, Dosage Form, and Strength: | (b) (4) (hydrochlorothiazide) for oral suspension, (b) (4) (b) (4) |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Novitium Pharma LLC (Novitium) |
| PNR ID #: | 2024-1044725798 |
| DMEPA 2 Safety Evaluator: | Jody Kundreskas, PharmD |
| DMEPA 2 Team Leader: | Nicole Iverson, PharmD, BCPS |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD |



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