CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216778Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	December 08, 2023
Application Type and Number:	Application Type Number/S-000
Product Name and Strength:	Zituvimet XR (established name) extended-release tablets, 50 mg/500 mg, 50 mg/1,000 mg, and 100 mg/1,000 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Choose an item
Applicant/Sponsor Name:	Zydus Pharmaceuticals (Zydus)
PNR ID #:	2023-1044725447
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Zituvimet XR, which was found conditionally acceptable under NDA 216778 on September 1, 2023.[a] Thus, Zydus submitted the name, Zituvimet XR, under NDA 216778 for review on November 2, 2023. We note that all product characteristics remain the same.

1.1 REGULATORY HISTORY

The applicant submitted a proprietary name request for Zituvimet XR on June 7, 2023, under NDA 216778. The name was found conditionally acceptable on September 1, 2023. However, this was prior to the formal NDA submission. NDA 216778 was formally submitted on September 22, 2023, and the applicant re-submitted the proprietary name review on November 2, 2023. There were no changes from the conditionally accepted proprietary name review and the current name review.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zituvimet XR would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Zituvimet XR. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Zituvimet XR.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 22, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Zituvimet XR.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On December 08, 2023, we communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

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, Zituvimet XR, is conditionally acceptable.

---

[a] McMillan, T. Proprietary Name Review for Zituvimet XR (NDA 216778). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Sep 01. PNR ID No. 2023-1044725174.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO ZYDUS PHARMACEUTICALS

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

If any of the proposed product characteristics as stated in your submission, received on November 2, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN 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/

VRAJ K PATEL
12/08/2023 01:09:28 PM

DAMON A BIRKEMEIER
12/08/2023 01:44:59 PM

MISHALE P MISTRY
12/08/2023 03:26:22 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	August 31, 2023
Application Type and Number:	NDA 216778
Product Name and Strength:	Zituvimet XR (sitagliptin and metformin hydrochloride) extended-release tablets, 50 mg/500 mg, 50 mg/1,000 mg and 100 mg/1,000 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Zydus Pharmaceuticals (Zydus)
PNR ID #:	2023-1044725174
DMEPA 1 Safety Evaluator:	Teresa McMillan, PharmD
DMEPA 1 Team Leader:	Idalia Rychlik, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Zituvimet XR, 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. Zydus did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Zydus previously submitted the proposed proprietary name Zituvimet *** (sitagliptin and metformin hydrochloride) immediate-release tablets under NDA 216743 on January 3, 2023. On March 27, 2023, we found the name, Zituvimet *** (sitagliptin and metformin hydrochloride) acceptable.[a] Under NDA 216778[b], Zydus is proposing sitagliptin and metformin hydrochloride extended-release tablets. Thus, Zydus submitted the name, Zituvimet XR (sitagliptin and metformin hydrochloride) extended-release tablets for review on June 7, 2023 under NDA 216778.

1.2 PRODUCT INFORMATION

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

Table 1. Relevant Product Information for Zituvimet XR and Zituvimet***

Product Name	Zituvimet XR	Zituvimet***
Initial Approval Date	N/A	N/A
Intended Pronunciation	zye too' vi met XR	zye too' vi met
Active Ingredient	sitagliptin and metformin hydrochloride extended release	sitagliptin and metformin hydrochloride
Indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	
Route of Administration	oral	
Dosage Form	extended-release tablets	tablets
Strength	50 mg/500 mg, 50 mg/1,000 mg and 100 mg/1,000 mg	50 mg/500 mg, 50 mg/1,000 mg
Dose and Frequency	The recommended starting dose in patients not currently treated	Take orally twice daily with meals. The maximum

[a] Conrad, A.. Proprietary Name Review for Zituvimet (NDA 216743). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 27. PNR ID No. 2023-1044724917.

[b] At the time of this review, NDA 216778 has not been filed; the PNR was submitted to the pre-NDA.

	with metformin is 100 mg sitagliptin and 1,000 mg metformin HCl extended-release once daily, with gradual dose escalation recommended to reduce gastrointestinal side effects associated with metformin. The starting dose in patients already treated with metformin should provide 100 mg sitagliptin and the previously prescribed dose of metformin. For patients taking metformin HCl immediate-release 850 mg twice daily or 1000 mg twice daily, the recommended starting dose of sitagliptin and metformin HCl extended-release Tablets is two 50 mg sitagliptin and 1000 mg metformin HCl extended-release tablets taken together once daily. Maintain the same total daily dose of sitagliptin and metformin when changing between sitagliptin and metformin HCl immediate-release and sitagliptin and metformin HCl extended-release tablets. Do not split, crush or chew sitagliptin and metformin HCl extended-release Tablets The maximum recommended daily dose is 100 mg of sitagliptin and 2000 mg of metformin HCl extended-release. **<u>Use in Renal Impairment</u>:** ***Sitagliptin and Metformin HCl extended-release Tablets:***	recommended daily dose is 100 mg of sitagliptin and 2,000 mg of metformin HCl. The recommended starting dose in patients not currently treated with metformin is 50 mg sitagliptin and 500 mg metformin HCl twice daily, with gradual dose escalation recommended to reduce gastrointestinal side effects associated with metformin. The starting dose in patients already treated with metformin should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and the dose of metformin already being taken. For patients taking metformin HCl 850 mg twice daily, the recommended starting dose of is 50 mg sitagliptin and 1000 mg metformin HCl twice daily. Prior to initiation, assess renal function with estimated glomerular filtration rate (eGFR) Do not use in patients with eGFR below 30 mL/min/1.73 m^2. Not recommended in patients with eGFR between 30 and less than 45 mL/min/1.73 m^2.

	It is contraindicated in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m2. Product is contraindicated in severe renal impairment, patients with an eGFR below 30 mL/min/1.73 m2. Initiation of product in patients with an eGFR between 30 and 45 mL/min/1.73 m2 is not recommended. The dose of the sitagliptin component should be limited to 50 mg once daily with benefit risk assessment, if eGFR falls below 45 mL/min/1.73 m2. ***Sitagliptin*** Sitagliptin is excreted by the kidney, and sitagliptin exposure is increased in patients with renal impairment. ***Metformin*** Metformin is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment. **<u>Hepatic Impairment</u>:** Use of metformin in patients with hepatic impairment has been associated with some cases of lactic acidosis. Product is not recommended in patients with hepatic impairment.	
How Supplied	**50/500 mg and 50/1,000 mg:** Bottle of 60's (b) (4) **100/1,000 mg:**	**50 mg/500 mg and 50 mg/1,000 mg:**

	Bottle of 30's (b) (4)	bottles of 60 or 180 tablets with child-resistant closures
Storage	20° to 25°C (68° to 77°F)	
Reference Listed Drug	Janumet XR (sitagliptin and metformin hydrochloride extended-release) NDA 202270	Janumet (sitagliptin and metformin hydrochloride) NDA 022044

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zituvimet XR would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Zituvimet XR. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Zituvimet XR.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name, Zituvimet XR, is comprised of two words: the root name 'Zituvimet' and the modifier 'XR'. The root name "Zituvimet***" (sitagliptin and metformin hydrochloride) was found conditionally acceptable on March 27, 2023, under NDA 216743.[d] However, NDA 216743 is still pending and has not been approved.

Zydus indicated in their submission that the proposed modifier 'XR', in the proposed proprietary name Zituvimet XR, is intended to convey that this drug product is an extended-release formulation for once-daily administration. We note that there is precedence for the use of the modifier XR which is approved by FDA for other extended-release products. See Section 2.2.5 for further evaluation of the proposed modifier 'XR'.

[c] USAN stem search conducted on June 30, 2023.

[d] Conrad, A.. Proprietary Name Review for Zituvimet (NDA 216743). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 27. PNR ID No. 2023-1044724917.

2.2.3 Comments from Other Review Disciplines at Initial Review

On June 30, 2023, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Zituvimet XR at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-six practitioners participated in DMEPA's prescription studies for Zituvimet XR. One participant in the inpatient written portion of the study identified the root name 'Zituvimet***' omitting the modifier 'XR'. At the time of this review, we note that Zituvimet*** is pending NDA approval, and the proposed proprietary name was found conditionally acceptable on March 27, 2023.[e] The omission of a modifier is evaluated in Section 2.25. Appendix B contains the results from the prescription simulation studies.

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.

2.2.5 Safety Analysis of Root Name, Zituvimet, and Modifier, XR

Zydus previously submitted the proposed proprietary root name Zituvimet *** (sitagliptin and metformin hydrochloride) immediate-release tablet formulation under NDA 216743 on January 3, 2023. On March 27, 2023, we found the name, Zituvimet *** (sitagliptin and metformin hydrochloride) conditionally acceptable.[f] At the time of this review, we note that NDA 216743 is pending approval. For their proposed sitagliptin and metformin hydrochloride extended-release tablets, Zydus proposes to use the name, Zituvimet XR. The differences between both formulations are listed in Table 1 under Section 1.2 of our review.

1. Evaluation of use of the same root name, "Zituvimet*"**

We note that Zituvimet*** and Zituvimet XR share the same active ingredients and indication of use. We previously evaluated the root name, Zituvimet*** under a separate review and did not identify any names that would pose a risk for confusion.[g] Thus, we do not object to the use of the root name, Zituvimet***, for this product.

2. Evaluation of the use of a modifier to differentiate the products

The proposed product represents a new dosage form (extended-release tablets vs. immediate-release tablets). Thus, the Applicant proposes to use the modifier "XR" to differentiate the proposed Zituvimet XR product from the proposed Zituvimet*** immediate-release product. We evaluated the use of a modifier to determine if the naming strategy helps to differentiate the proposed Zituvimet XR product from the proposed Zituvimet product.

---

[e] Conrad, A.. Proprietary Name Review for Zituvimet (NDA 216743). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 27. PNR ID No. 2023-1044724917.

[f] Conrad, A.. Proprietary Name Review for Zituvimet (NDA 216743). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 27. PNR ID No. 2023-1044724917.

[g] Conrad, A.. Proprietary Name Review for Zituvimet (NDA 216743). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 27. PNR ID No. 2023-1044724917.

It is not uncommon to use modifiers to denote a specific product formulation as part of a product line extension. The addition of a modifier may signal to healthcare practitioners that this product differs from the proposed Zituvimet*** product.

We also considered the risk of name confusion if the modifier is omitted or overlooked, as seen in the FDA Prescription Simulation Study. We note that omission and oversight of a modifier is cited in literature as a common cause of medication errors.[h] Postmarketing experience shows that the introduction of product line extensions may result in medication errors if the modifier is omitted, and the product characteristics are similar or overlap. In this case, we note that both the proposed immediate-release tablets and proposed extended-release tablets will be available in 50 mg/500 mg and 50 mg/1,000 mg strength tablets. Therefore, this overlapping product characteristic may be a risk of medication errors if the modifier is omitted or overlooked.

As part of our evaluation of the appropriateness of the modifier "XR", we consulted with the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) Medical officer to determine the clinical significance of patient harm (if any) if the products were to be confused for one another. For example:

- If a patient intended to receive Zituvimet XR (extended release) 50 mg/500 mg or 50 mg/1,000 mg once daily but instead receives Zituvimet *** (immediate release) 50 mg/500 mg or 50 mg/1,000 mg and proceeds to take it once daily.
- If a patient intended to receive Zituvimet*** (immediate release) 50 mg/500 mg or 50 mg/1,000 mg twice daily but instead receives Zituvimet XR (extended release) 50 mg/500 mg or 50 mg/1,000 mg and proceeds to take it twice daily.

According to the medical officer via email communication on July 25, 2022, no significant issues are expected if scenario #1 occurs. However, some nonserious gastrointestinal side effects could occur with the second scenario described above. Therefore, from a clinical perspective there is minimal concern if these products were to be confused for one another.

We also note the extended-release formulation is administered once daily vs. the immediate release is administered twice daily. The frequency of administration would also serve as a differentiating factor to help mitigate formulation confusion and/or selection medication errors.

Although the proposed naming strategy is not devoid of risk because modifiers may be omitted, they can assist in differentiating products and may help to prevent potential selection medication errors when used. Thus, based on the totality of this information, we do not object to the use of a modifier for this product as it may provide an added measure of safety. Furthermore, label and labeling mitigations can help minimize the residual risk of product selection medication errors.

3. Evaluation of the proposed modifier, "XR"

The Applicant proposes the modifier "XR" to denote that the product is an extended-release formulation with a once daily frequency of administration. We note that the use of the modifier "XR" to convey that the proposed product is an extended-release dosage form is contingent upon the product meeting the Agency's criteria for this designation. Assuming these criteria are met, we note that products with the modifier "XR" have been approved in cases where a product is administered "every 12 hours", "twice daily", or "once daily" dosing schedule for an extended-

[h] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

release formulation. Based on the Institute for Safe Medication Practices (ISMP) List of Products with Drug Name Suffixes, the modifier "XR" is typically used to convey the meaning "extended-release" for products with modified-release formulations.[i] As the proposed product will be dosed once daily, the use of the modifier "XR" is consistent with its existing meaning and is appropriate for conveying the extended-release characteristic of this product formulation.

Therefore, we do not object to the use of modifier "XR" for the proposed product and find that "XR" is acceptable for conveying this characteristic of the product formulation.

In summary, we find the use of the root name, Zituvimet conditionally acceptable for the proposed product. Additionally, we find that the addition of the modifier "XR" to the root name may provide an additional layer of safety in differentiating the proposed extended-release tablets from the currently marketed immediate-release tablets. Although the naming strategy presents some risk of product selection error if the modifier is dropped, we find the residual risk acceptable based on input from the clinical team and due to the difference in frequency of administration. Therefore, based on the totality of information considered above, we do not object to the proposed name, Zituvimet XR, for the proposed product.

2.2.6 Communication of DMEPA's Determination

On August 31, 2023, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Zituvimet XR, is conditionally acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO ZYDUS PHARMACEUTICALS

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

If any of the proposed product characteristics as stated in your submission, received on June 7, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

[i] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

4 REFERENCES

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [j]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

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

Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or

during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

c. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

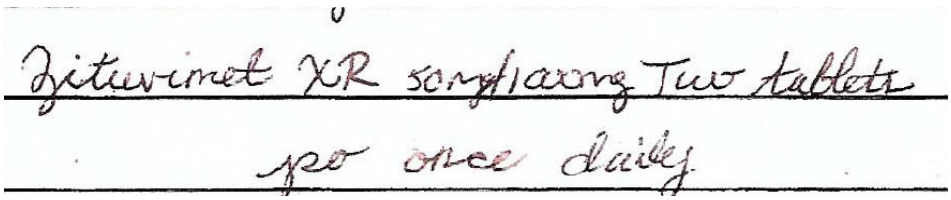
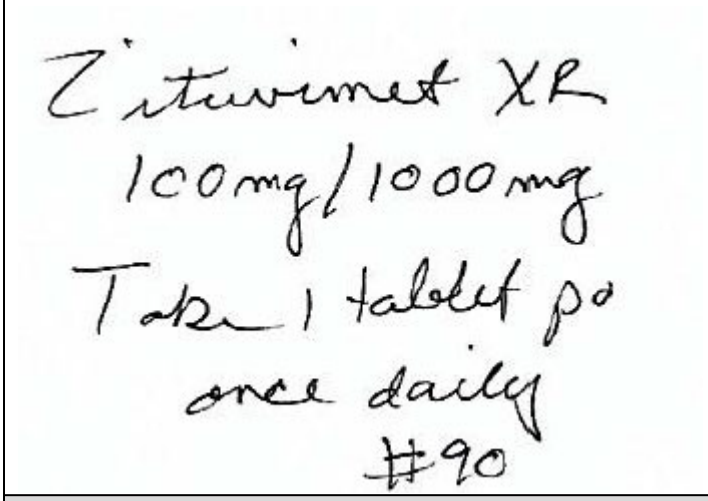
Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Zituvimet XR Study (Conducted on July 7, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Zituvimet XR 100 mg/1000 mg Take 1 tablet po once daily #90
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Zituvimet XR	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Zituvimet XR - 2023-07-07 People Received Study: 254 People Responded: 86					
Total	24	21	21	20	86
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ZATUMATAT XR	0	0	1	0	1
ZATUVAMET XR	0	0	1	0	1
ZETUBAMET XR	0	0	1	0	1
ZETUBAMETH XR	0	0	1	0	1
ZETUVAMAB XR	0	0	1	0	1
ZETUVAMET XR	0	0	5	0	5
ZETUVIMET XR	0	0	2	0	2
ZIPTUBMAT	0	0	1	0	1
ZITAVIMET XR	1	0	0	0	1
ZITIEVIMET XR	1	0	0	0	1
ZITREVIMET XR	1	0	0	0	1
ZITUBAMEP XR	0	0	1	0	1
ZITUBETMET XR	0	0	1	0	1
ZITUEVIMET XR	1	0	0	0	1
ZITUVAMET XR	0	0	3	0	3
ZITUVIMEB XR	0	0	1	0	1
ZITUVIMET	1	0	0	0	1
ZITUVIMET XR	17	18	0	20	55
ZITUVIMET XT	1	2	0	0	3
ZITUVINET XR	0	1	0	0	1
ZITUVINMET XR	1	0	0	0	1

ZUTUBAMET XR	0	0	1	0	1
ZUTUVAMET XR	0	0	1	0	1

** U.S. FDA - RX Study*
** RX Study Version 4.2 (2023-07-12)*

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/

TERESA S MCMILLAN
08/31/2023 04:45:39 PM

IDALIA E RYCHLIK
08/31/2023 05:26:26 PM

MISHALE P MISTRY
09/01/2023 10:00:09 AM