CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218879Orig1s000

PROPRIETARY NAME REVIEWS

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:	May 13, 2025
Application Type and Number:	NDA 218879
Product Name, Dosage Form, and Strength:	Subvenite (lamotrigine) oral suspension, 10 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	OWP Pharmaceuticals, Inc. (OWPP)
PNR ID #:	2025-1044726338
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Subvenite.

Torrent Pharmaceuticals, Ltd previously submitted the proposed proprietary name, Subvenite, for lamotrigine tablets under ANDA 078947/S-026 on June 16, 2017. We performed a full safety assessment and found the name, Subvenite acceptable for lamotrigine tablets under ANDA 078647/S-026 on September 5, 2017.[a]

OWOS Pharmaceutical LP, the owner of the Subvenite name, submitted the name, Subvenite, for lamotrigine oral suspension for review under IND 140073 on July 8, 2021. Torrent Pharmaceuticals and OWOS Pharmaceuticals have a business relationship. Since Subvenite was a currently approved name for a marketed product we performed an abbreviated safety assessment, which included a FAERS search for medication error reports involving name confusion with Subvenite. We found the name, Subvenite, conditionally acceptable under IND 140073 on November 23, 2021.[b]

Thus, OWPP submitted the proposed proprietary name, Subvenite, under NDA 218879 for review on March 11, 2024. Aside from the change in package size to only include an 8-ounce bottle presentation for NDA 218879 compared to the proposed 8-ounce and (b) (4) bottles proposed under IND 140073, all other product characteristics remain the same. We found the name, Subvenite, conditionally acceptable under NDA 218879 on June 3, 2024.[c] However, NDA 218879 received a complete response due to product quality issues.

Thus, OWPP submitted the proposed proprietary name, Subvenite, under the class 2 resubmission for NDA 218879 for re-review on March 17, 2025.[d] We note that all product characteristics remain the same since our last review.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

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[a] Morris, C. Proprietary Name Review for Subvenite tablets (ANDA 079847/S-026). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 SEP 05. PNR ID No. 2017-15797679.

[b] Morris, C. Proprietary Name Review for Subvenite oral suspension (NDA 218879). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 NOV 23. PNR ID No. 2021-1044724054.

[c] Morris, C. Proprietary Name Review for Subvenite (NDA 218879). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 JUN 03. PNR ID No. 2024-1044725669.

[d] Cover Letter: Resubmission, Response to CRL (includes request for PNR) for NDA 218879. Lenexa (KS): OWP Pharmaceuticals, Inc.; 2025 MAR 16. Available from: \\CDSESUB1\EVSPROD\nda218879\0024\m1\us\12-cover-letters\cover-letter-03-16-2025.pdf.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Subvenite, we considered any lessons learned from recent post-marketing experience that may alter our previous conclusion regarding the acceptability of the proposed proprietary name. Therefore, on March 25, 2025, we searched the FDA Adverse Event Reporting System (FAERS) database (see Appendix A for our search criteria and a description of FAERS database) for name confusion errors involving Subvenite that would be relevant for this review. Our search did not yield any reports describing name confusion for Subvenite. Therefore, this evaluation of the proposed name does not alter our previous conclusion regarding the acceptability of the proposed proprietary name, Subvenite.

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 March 25, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name, Subvenite.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On May 6, 2025, DMEPA 2 communicated our determination to the Division of Neurology 2.

3 CONCLUSION

Our re-assessment did not identify any new sources of drug name confusion. Therefore, we maintain that the proposed proprietary name, Subvenite, is conditionally acceptable.

3.1 COMMENTS TO OWP PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 17, 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.

APPENDIX A. FDA Adverse Event Reporting System (FAERS)

Table 1. FAERS Search Strategy	
FAERS Field	Search Terms
Initial FDA Receive Dates	April 23, 2024 to March 25, 2025
Product Name	Subvenite
Drug Role	Suspect
Event	DMEPA Official PNR Name Confusion Search Terms
Country (derived)	USA

Our search did not yield any reports describing name confusion involving Subvenite.

Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

STEPHANIE L DEGRAW
05/13/2025 03:55:20 PM

HINA S MEHTA
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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)

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Date of This Review:	June 3, 2024
Application Type and Number:	NDA 218879
Product Name, Dosage Form, and Strength:	Subvenite (lamotrigine) oral suspension, 10 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	OWP Pharmaceuticals, Inc. (OWPP)
PNR ID #:	2024-1044725669
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Subvenite.

Torrent Pharmaceuticals, Ltd previously submitted the proposed proprietary name, Subvenite, for lamotrigine tablets under ANDA 078947/S-026 on June 16, 2017. We performed a full safety assessment and found the name, Subvenite acceptable for lamotrigine tablets under ANDA 078647/S-026 on September 5, 2017.[a]

OWOS Pharmaceutical LP, the owner of the Subvenite name, submitted the name, Subvenite, for lamotrigine oral suspension for review under IND 140073 on July 8, 2021. Torrent Pharmaceuticals and OWOS Pharmaceuticals have a business relationship. Since Subvenite was a currently approved name for a marketed product we performed an abbreviated safety assessment, which included a FAERS search for medication error reports involving name confusion with Subvenite. We found the name, Subvenite, conditionally acceptable under IND 140073 on November 23, 2021.[b]

OWP Pharmaceuticals, Inc. (OWPP) submitted NDA 218879 on March 4, 2024, but did not include a request for proprietary name review, so the Agency sent an information request (IR) on March 6, 2024, requesting OWPP to submit a proprietary name request for review if they still intend to pursue a proprietary name for lamotrigine oral suspension under NDA 218879.[c]

Thus, OWPP submitted the proposed proprietary name, Subvenite, under NDA 218879 for review on March 11, 2024.[d] We note that there is a change in package size to only include an 8-ounce bottle presentation for NDA 218879 compared to the proposed 8-ounce (b) (4) bottles proposed under IND 140073. All other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Subvenite 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 Subvenite. The Division of Neurology 2 (DN 2) did not comment on the findings of OPDP's assessment for Subvenite.

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[a] Morris, C. Proprietary Name Review for Subvenite tablets (ANDA 079847/S-026). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 SEP 05. PNR ID No. 2017-15797679.

[b] Morris, C. Proprietary Name Review for Subvenite oral suspension (IND 140073). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 NOV 23. PNR ID No. 2021-1044724054.

[c] Webster, M. Proprietary Name Information Request (NDA 218879). 2024 MAR 06. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8072e0b0

[d] Request for Proprietary Name Review for Subvenite (lamotrigine) oral suspension NDA 218879. Lenexa (KS): OWP Pharmaceuticals, Inc.; 2024 MAR 09. Available from: \\CDSESUB1\EVSPROD\nda218879\0004\m1\us\12-cover-letters\cover-letter-03-09-2024.pdf .

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Subvenite, we considered any lessons learned from recent post-marketing experience that may alter our previous conclusion regarding the acceptability of the proposed proprietary name. Therefore, on April 22, 2024, we searched the FDA Adverse Event Reporting System (FAERS) database (see Appendix A for our search criteria and a description of FAERS database) for name confusion errors involving Subvenite that would be relevant for this review. Our search did not yield any reports describing name confusion for Subvenite. Additionally, we determined the change in proposed packaging presentation is unlikely to introduce new risks for name confusion not previously considered. Therefore, this evaluation of the proposed name, Subvenite, does not alter our previous conclusion regarding the acceptability of the proposed proprietary name, Subvenite.

We also searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 22, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Subvenite.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On June 1, 2024, DMEPA 2 communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

Our re-assessment did not identify any new sources of drug name confusion. Therefore, we maintain that the proposed proprietary name, Subvenite, is conditionally acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO OWP PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 11, 2024, 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.

APPENDICIES

APPENDIX A. FDA Adverse Event Reporting System (FAERS)

Table 1. FAERS Search Strategy	
FAERS Field	Search Terms
Initial FDA Receive Dates	No limits
Product Name	Subvenite
Drug Role	Suspect
Event	DMEPA Official PNR Name Confusion Search Terms
Country (derived)	USA

Our search did not yield any reports describing name confusion involving Subvenite.

Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

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