CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219616Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	March 19, 2025
Application Type and Number:	NDA 219616
Product Name, Dosage Form, and Strength:	Avmapki Fakzynja Co-Pack (avutometinib capsules, 0.8 mg; defactinib tablets, 200 mg)
Product Type:	Co-packaged Single Ingredient Products
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Verastem, Inc (Verastem)
PNR ID #:	2025-1044726249
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Avmapki Fakzynja Co-Pack, 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. Verastem did not submit an external name study for this proposed proprietary name, Avmapki Fakzynja Co-Pack. Verastem previously submitted external name studies, conducted by (b) (4) [ab] for the proposed proprietary root names Avmapki and Fakzynja. The submitted external name studies were previously reviewed under IND 151352 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Verastem previously submitted the proposed proprietary names, Avmapki, and, Fakzynja, under NDA 219616 on May 31, 2024 and we found the names conditionally acceptable on August 23, 2024.[c,d]

We noted that Verastem used the modifier "Co-Pack" next to the proposed proprietary names, Avmapki, and, Fakzynja, in the proposed carton labeling received on October 31, 2024. After internal discussion with the review team, on December 16, 2024, we sent an information request to Verastem to submit "Avmapki Fakzynja Co-Pack" for review[e]. On January 24, 2025, we met with Verastem via teleconference to discuss the recommendation of a third proposed proprietary name for the co-packaged carton of Avmapki and Fakzynja.[f]

Thus, Verastem submitted the proposed proprietary name, Avmapki Fakzynja Co-Pack, for review on January 27, 2025 under NDA 219616.

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[a] Proprietary Name Safety Summary for Avmapki. (b) (4) 2022 AUG 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0022\m1\us\118-proprietary-names\proprietary-name.pdf.

[b] Proprietary Name Safety Summary for Fakzynja. (b) (4) 2022 Aug 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0001\m1\us\118-proprietary-names\proprietary-name-safety-sum-fakzynja.pdf.

[c] Mahmoud, S. Proprietary Name Review for Avmapki (NDA 219616). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 23. PNR ID No. 2024-1044725821.

[d] Mahmoud, S. Proprietary Name Review for Fakzynja (NDA 219616). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 23. PNR ID No. 2024-1044725822.

[e] Fahnbulleh, F. Proprietary Name Information Request for NDA 219616 Aavutometinib Capsules; Defactinib Tablets. Silver Spring (MD): FDA, CDER, OSE (US); 2024 DEC 16. NDA 219616. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8078a4cb

[f] Fahnbulleh, F. Teleconference Meeting Minutes for NDA 219616. Silver Spring (MD): FDA, CDER, OSE (US); 2025 MAR 11. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af807a4388

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 27, 2025[g] and the prescribing information received on October 31, 2024.[h]

<table>
<tr><th colspan="3">Table 1. Relevant Product Information for Avmapki Fakzynja Co-Pack</th></tr>
<tr><td>Intended pronunciation:</td><td colspan="2">AVMAPKI (ave-MAP-kee) FAKZYNJA (Fak-zin-jah) Co-Pack (co-pac)</td></tr>
<tr><td>Proprietary Name</td><td>Avmapki</td><td>Fakzynja</td></tr>
<tr><td>Active ingredients:</td><td>avutometinib</td><td>defactinib</td></tr>
<tr><td>Indication:</td><td colspan="2">• Treatment of patients with recurrent low grade serous ovarian cancer (LGSOC) after at least one prior therapy (b) (4)
(b) (4)</td></tr>
<tr><td>Dosage Form:</td><td>capsules</td><td>tablets</td></tr>
<tr><td>Strength:</td><td>0.8 mg</td><td>200 mg</td></tr>
<tr><td>Route of administration:</td><td colspan="2">Oral</td></tr>
<tr><td>Dose and frequency:</td><td>3.2 mg (four capsules) 2 times weekly (Day 1 and Day 4) for 3 weeks, followed by 1 week rest period, in each 4-week (28 day) cycle.

Dosage modification:<table><tr><th>Dose Level</th><th>AVMAPKI Capsule</th></tr><tr><td>Starting dose</td><td>3.2 mg twice weekly for 3 of 4 weeks</td></tr><tr><td>First dose reduction</td><td>2.4 mg twice weekly for 3 of 4 weeks</td></tr><tr><td>Second dose reduction</td><td>1.6 mg twice weekly for 3 of 4 weeks</td></tr></table></td><td>200 mg (one tablet) twice daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

Dose modification:<table><tr><th>Dose Level</th><th>FAKZYNJA Tablet</th></tr><tr><td>Starting dose</td><td>200 mg twice daily for 3 of 4 weeks</td></tr><tr><td>Dose reduction</td><td>200 mg once daily for 3 of 4 weeks</td></tr></table></td></tr>
<tr><td>How Supplied:</td><td colspan="2">1 carton containing 2 co-packaged bottles</td></tr>
</table>

[g] Proposed Proprietary Name. Needham (MA): Verastem, Inc; 2025 JAN 27. Available from: \\CDSESUB1\EVSPROD\nda219616\0022\m1\us\118-proprietary-names\proprietary-name.pdf.

[h] Proposed prescribing information for Avmapki Fakzynja Co-Pack. Needham (MA): Verastem, Inc; 2024 OCT 31. Available from: \\CDSESUB1\EVSPROD\nda219616\0003\m1\us\114-labeling\draft\annotated\annotated-word.docx.

Table 1. Relevant Product Information for Avmapki Fakzynja Co-Pack		
	One round white plastic bottle with a child resistant cap and induction seal. Bottle also contains a 2 g desiccant. Bottle contains 18 or 24 capsules.	One round white plastic bottle with a child resistant cap and induction seal. Bottle contains 42 tablets.
Storage:	Keep AVMAPKI capsules and FAKZYNJA tablets refrigerated at 2°C to 8°C (36°F to 46°F) in their original bottles.	

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Avmapki Fakzynja Co-Pack.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Avmapki Fakzynja Co-Pack 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 Avmapki Fakzynja Co-Pack. The Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Avmapki Fakzynja Co-Pack.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Avmapki Fakzynja Co-Pack.

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Verastem did not provide a derivation or intended meaning for the proposed proprietary name, Avmapki Fakzynja Co-Pack, in their submission. This proprietary name is comprised of three words that contain two root names and a modifier 'Co-Pack', and contain the letter strings "ac", which is medical abbreviations for "after meal". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviation "ac" in the middle of the modifier, 'Co-Pack', makes it unlikely for the "ac" letter string to be separated from the surrounding letters in a manner that could lead to confusion. Furthermore, we have no expectation that the word, 'Co-Pack', would be spelled differently to

[i] USAN stem search conducted on February 27, 2025.

avoid containing a medical abbreviation. Thus, we do not object to the inclusion of the "ac" letter string in this case.

Beyond these noted abbreviations, we note that PPN does not contain any additional components (i.e., modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

We further evaluated the proposed modifier, "Co-Pack" in section 2.2.5.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Avmapki Fakzynja Co-Pack at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-six (96) practitioners participated in DMEPA's prescription simulation studies for Avmapki Fakzynja Co-Pack.

Two inpatient study participants and one outpatient study participant provided the response "Avmapki" only and omitted the second root name "Fakzynja" and the modifier "Co-Pack". One inpatient study participant provided the response "AUMAPKI FAKZYNJA" and omitted the modifier "Co-Pack". We further evaluate the risk of name confusion if the second root name "Fakzynja" and the modifier "Co-Pack" are dropped in Section 2.2.5 below.

The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 SAFETY ANALYSIS OF THE PROPOSED MODIFIER, "CO-PACK"

The proposed proprietary name, Avmapki Fakzynja Co-pack, is comprised of the root names, "Avmapki" and "Fakzynja", and the modifier "Co-Pack". Verastem proposed the modifier "Co-Pack" to denote that Avmapki and Fakzynja will be co-packaged and marketed as a co-packaged product.

We note that the use of the modifier "Co-Pack" to convey that the proposed product's packaging includes one or more drug products that are to be used in conjunction with each other (e.g., Avmapki Fakzynja Co-Pack). The term, Co-Pack, may also be used in cases where the packaging configuration is designed with an intent to improve patient adherence and/or minimize the likelihood of medication errors that may be associated with the product's dosage regimen. The proposed product will be packaged in a carton containing two bottles. One bottle will contain Avmapki (b) (4) 24 capsules, and one bottle will contain Fakzynja 42 tablets. These two products will be used concomitantly for the treatment of low grade serous ovarian cancer (b) (4). Thus, this is consistent with how the modifier, Co-Pack, has been employed in drug nomenclature for similar circumstances.

We note that omission and oversight of modifiers is cited in literature as a common cause of medication errors.[j] In this case, there are no other products currently marketed under the root name "Avmapki" or "Fakzynja" that could be dispensed in error.

We also note that the second root name, "Fakzynja" may be omitted in error due to unfamiliarity with the product. In this case, Avmapki is proposed to be supplied and distributed in the co-packaged "Avmapki Fakzynja Co-pack" carton only. Thus, there will not be a product marketed under the root name "Avmapki" that could be dispensed in error. Additionally, it is reasonable to expect that, like any novel product, awareness among healthcare providers will increase with market uptake of the product.

Therefore, we do not object to the use of the modifier "Co-Pack" for the proposed proprietary name "Avmapki Fakzynja Co-Pack", and find that the modifier "Co-Pack" is acceptable.

2.2.6 COMMUNICATION OF DMEPA'S DETERMINATION

On March 19, 2025, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

The proposed proprietary name, Avmapki Fakzynja Co-Pack, is conditionally acceptable.

3.1 COMMENTS TO VERASTEM, INC

We have completed our review of the proposed proprietary name, Avmapki Fakzynja Co-Pack, and have concluded that this proprietary name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission, received on January 27, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

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

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.

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.[k]

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 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?

[k] 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.	
	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 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.

c. 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 and 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.

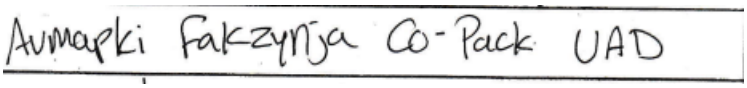
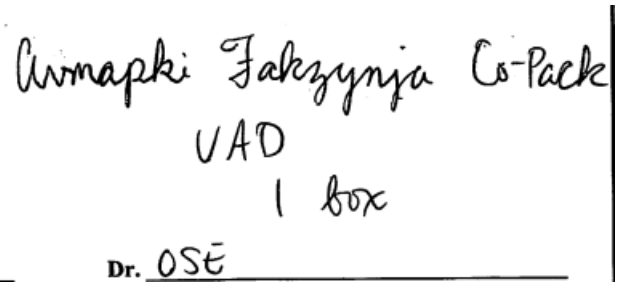
   Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

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.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Avmapki Fakzynja Co-Pack Study (Conducted on 2/7/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Avmapki Fakzynja Co-Pack Use as directed. Dispense 1 box
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Avmapki Fakzynja Co-Pack	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Avmapki Fakzynja Co-Pack People Received Study: 167 People Responded: 96					
Total	26	24	20	26	96
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ABNAKETASINGA TOEPACK	0	0	1	0	1
AFMAKI FASINGA COPAK	0	0	1	0	1
AFMATKE FEXINJA COPACK	0	0	1	0	1
AFMEPQVIFEXINGA COPEC	0	0	1	0	1
AIMPAKI FAKZYNJA CO-PACK	0	1	0	0	1
ARMAPKI FAKZYNJA CO-PACK	0	3	0	0	3
ARMPAKI FAKZYNJA CO-PACK	0	1	0	0	1
ARSMAPKI TAKZYNJA CO-PACK	0	1	0	0	1
ASMAKIFEXINGA COPACK	0	0	1	0	1
ASMAPQI/VAXINGA COPACK	0	0	1	0	1
AUMAPKI FAKZYNJA	1	0	0	0	1

AUMAPKI FAKZYNJA CO-PACK	8	0	0	0	8
AUMPKI FAKZYNJA CO-PACK	0	1	0	0	1
AVIMAPKI FAKZYNJA CO-PACK	1	0	0	0	1
AVMABXI FAXING COPACK	0	0	1	0	1
AVMAKEFAXINZA COPACK	0	0	1	0	1
AVMAKY FASINGA COPACK	0	0	1	0	1
AVMAOKI VACCINE-JEU COPACK	0	0	1	0	1
AVMAPKE FAXINGA COPAK	0	0	1	0	1
AVMAPKEY FACINGA CO-PACK	0	0	1	0	1
AVMAPKI	2	1	0	0	3
AVMAPKI FAKSINJA COPAK	0	0	1	0	1
AVMAPKI FAKYYNJA CO-PACK	0	1	0	0	1
AVMAPKI FAKZYNHA CO-PACK	1	0	0	0	1
AVMAPKI FAKZYNJA CO PACK	0	1	0	0	1
AVMAPKI FAKZYNJA CO-PACK	11	12	0	26	49
AVMAPKI FAKZYNJA CO-PACK VAD	0	1	0	0	1
AVMAPKI FAKZYNJA CO-PAK	1	0	0	0	1
AVMAPKI KAKZYNJA CO-PACK	1	0	0	0	1
AVMAPKY FAKSINGA COPAK	0	0	1	0	1
AVMAPKY FAXINJA CO-PACK	0	0	1	0	1
AVMAPKY FAXINJA COPACK	0	0	1	0	1
AVMAPKY/FAXINJA CO-PACK	0	0	1	0	1
AVMAPQI VAXENJA COPACK	0	0	1	0	1
AZMABKI FAXZINGA COPAK	0	0	1	0	1
AZMAPKEY VAZINZA CO-PACK	0	0	1	0	1
CURMAPKI FAKZYNJA CO-PACK	0	1	0	0	1

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/

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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 23, 2024
Application Type and Number:	NDA 219616
Product Name, Dosage Form, and Strength:	Fakzynja (defactinib) tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Verastem, Inc. (Verastem)
PNR ID #:	2024-1044725822
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Acting Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Fakzynja, 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. Verastem submitted an external name study, conducted by [redacted][a], for this proposed proprietary name. The submitted external name study was previously reviewed under IND 151352 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Verastem previously submitted the proposed proprietary name, Fakzynja, under IND 151352 on August 31, 2022, and we found the name conditionally acceptable on April 27, 2023.[b]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 31, 2024[c].

Table 1. Relevant Product Information for Fakzynja	
Intended pronunciation:	fak zin' jah
Active ingredient:	defactinib
Indication:	Treatment of patients with recurrent low grade serous ovarian cancer (LGSOC) after at least one prior therapy [redacted]
Dosage Form:	tablets
Strength:	200 mg
Route of administration:	Oral
Dose and frequency:	200 mg (1 tablet) twice daily for 3 weeks, followed by 1-week rest period, in each 4-week (28 day) cycle.

[a] Proprietary Name Safety Summary for FAKZYNJA. [redacted] 2022 Aug 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0001\m1\us\118-proprietary-names\proprietary-name-safety-sum-fakzynja.pdf

[b] Gao, T. Proprietary Name Review for Fakzynja (IND 151352). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 APR 27. PNR ID No. 2022-1044724972.

[c] Proprietary Name Safety Summary for FAKZYNJA. [redacted] 2022 Aug 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0001\m1\us\118-proprietary-names\proprietary-name-safety-sum-fakzynja.pdf

Table 1. Relevant Product Information for Fakzynja	
How Supplied:	Round white plastic bottle with a child resistant cap and induction seal. Bottle contains 42 tablets.
Storage:	After use, store (b) (4) in a refrigerator

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Fakzynja 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 Fakzynja. The Division of Oncology 1 (DO1) did not comment on the findings of OPDP's assessment for Fakzynja.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Fakzynja at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety (n= 90) practitioners participated in DMEPA's prescription studies for Fakzynja.

[d] USAN stem search conducted on July 3, 2024.

One respondent in the Inpatient study misinterpreted the proposed proprietary name as "Takzynja", which is similar to the currently marketd product, Takhzyro. The name pair Fakzynja and Takhzyro was previously reviewed under IND 151352.[e]

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name "Fazaclo". However, the participant entered an incorrect sequence of letters, 'Faz' when searching for the study name. As a result, the CPOE generated picklist did not contain Fakzynja as a choice. It's likely the participant proceeded to incorrectly select Fazaclo as their response 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 Fakzynja vs. Fazaclo and determined that this name pair has sufficient orthographic and phonetic differences.

Orthographically, Fakzynja contains downstrokes letters 'y' and 'j' in the 5th and 7th positions, which is not present in Fazaclo. Fazaclo also has an upstroke letter 'l' in the 6th position , whereas Fakzynja does not.

Phonetically, the second syllable ('zin' vs 'ah') and third syllables ('jah' vs 'kloe') sound different.

In addition to orthographic and phonetic differences, the products differ in dose (200 mg vs. 12.5 mg to 900 mg). Also, FazaClo (clozapine) is under the Clozapine REMS program. Notable requirements of the clozapine REMS Program include the following:

1. Patients must be enrolled in the clozapine REMS by a certified doctor.
2. Pharmacies must be certified clozapine REMS to receive and dispense clozapine.
3. Prescribers must be certified in the clozapine REMS to prescribe clozapine for outpatient use.

When all of the aforementioned mitigations are considered, we find the risk of confusion is adequately minimized in this case.

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[f] identified 16 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our

[e] Gao, T. Proprietary Name Review for Fakzynja (IND 151352). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 APR 27. PNR ID No. 2022-1044724972.

[f] POCA search conducted on July 3, 2024 in version 5.9.

previous review for the names evaluated previously. Therefore, we did not identify any new names that were not previously analyzed.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our FDA Prescription Simulation 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: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	0
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 1 name contained in Table 2 determined none of the names will pose a risk for confusion with Fakzynja as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On August 23, 2024, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

The proposed proprietary name, Fakzynja, is conditionally acceptable.

3.1 COMMENTS TO VERASTEM, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 31, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

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.[g]

*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 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.

[g] 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 ≥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[h]. 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.

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

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 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? *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? **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?	

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? • *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

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. Fakzynja Study (Conducted on 6/7/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: Fakzynja Take 1 tablet now	Fakzynja Take 1 tablet by mouth twice daily for 3 weeks then stop for 1 week. #42
Outpatient Prescription: ℞ Fakzynja 200mg 1 tab PO BID x3w then stop x1w #42 MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr._____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Fakzynja	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Fakzynja People Received Study: 196 People Responded: 90					
Total	20	28	20	22	90
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BACLOVENGA	0	0	1	0	1
BACZINJA	0	0	1	0	1
BAKZINJA	0	0	1	0	1
FABZYNJA	2	0	0	0	2
FABZYRUA	1	0	0	0	1
FACAZINGA	0	0	1	0	1
FACOZENJA	0	0	1	0	1
FACTAZINGA	0	0	1	0	1
FACTAZINJA	0	0	2	0	2
FACTAZYNJA	0	0	1	0	1
FACTICINZA TABLETS	0	0	1	0	1
FACTIZINJA	0	0	1	0	1
FACTZYNJA	0	0	1	0	1
FACZINGA	0	0	1	0	1
FACZINJA	0	0	4	0	4
FAKYYNJA	1	0	0	0	1
FAKZYERJA	0	1	0	0	1
FAKZYIJA	0	1	0	0	1
FAKZYINJA	0	1	0	0	1
FAKZYIRJA	0	1	0	0	1
FAKZYIYA	0	1	0	0	1
FAKZYNIA	1	0	0	0	1
FAKZYNJA	14	17	0	21	52
FAKZYRIJA	0	1	0	0	1
FAKZYRJA	0	4	0	0	4
FAKZYUJA	0	1	0	0	1
FAQAXINGA	0	0	1	0	1
FAZACLO	0	0	0	1	1
TAKZYNJA	1	0	0	0	1
VACZINJA	0	0	2	0	2

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

No.	Proposed name: Fakzynja Pronunciation: fak zin' jah Established name: defactinib Dosage form: tablets Strength(s): 200 mg Dosage: 200 mg (1 tablet) by mouth twice daily for three weeks then stop for one week.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
	N/A		

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 (%)
	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: Fakzynja Pronunciation: fak zin' jah Established name: defactinib Dosage form: tablets Strength(s): 200 mg Dosage: 200 mg (1 tablet) by mouth twice daily for three weeks then stop for one week.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Fazaclo	48	*See FMEA in Section 2.2.4*

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

No.	Name	POCA Score (%)
	N/A	

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
	N/A		

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

No.	Name	POCA Score (%)
	N/A	

[i] 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 23, 2024
Application Type and Number:	NDA 219616
Product Name, Dosage Form, and Strength:	Avmapki (avutometinib) capsules, 0.8 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Verastem, Inc (Verastem)
PNR ID #:	2024-1044725821
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Acting Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Avmapki, 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. Verastem submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external name study was previously reviewed under IND 151352 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Verastem previously submitted the proposed proprietary name, Avmapki, under IND 151352 on August 31, 2022, and we found the name conditionally acceptable on April 27, 2023.[b]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 31, 2024[c].

Table 1. Relevant Product Information for Avmapki	
Intended pronunciation:	av map' kee
Active ingredient:	avutometinib
Indication:	• Treatment of patients with recurrent low grade serous ovarian cancer (LGSOC) after at least one prior therapy (b) (4) (b) (4)
Dosage Form:	capsules
Strength:	0.8 mg
Route of administration:	Oral
Dose and frequency:	(b) (4) mg ((b) (4) capsules) 2 times weekly for 3 weeks, followed by 1 week rest period, in each 4-week (28 day) cycle

[a] Proprietary Name Safety Summary for AVMAPKI. (b) (4) 2022 AUG 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0001\m1\us\118-proprietary-names\proprietary-name-safety-sum-avmapki.pdf

[b] Gao, T. Proprietary Name Review for Avmapki (IND 151352). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 APR 27. PNR ID No. 2022-1044724730.

[c] Proprietary Name Safety Summary for AVMAPKI. (b) (4) 2022 AUG 23. Available from: \\CDSESUB1\EVSPROD\nda219616\0001\m1\us\118-proprietary-names\proprietary-name-safety-sum-avmapki.pdf

Table 1. Relevant Product Information for Avmapki	
How Supplied:	Round white plastic bottle with a child resistant cap and induction seal. Bottle also contains a 2 g desiccant. Number of capsules in a bottle will be (b) (4) 24 (b) (4)
Storage:	After use, store (b) (4) in a refrigerator.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Avmapki 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 Avmapki. The Division of Oncology 1 (DO1) did not comment on the findings of OPDP's assessment for Avmapki.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Avmapki at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety (n= 90) practitioners participated in DMEPA's prescription simulation studies for Avmapki. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

[d] USAN stem search conducted on July 3, 2024.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[e] identified 13 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. We did not identify any new names that were not previously analyzed. Therefore, we did not identify any names that could pose a risk for confusion with Avmapki.

2.2.6 COMMUNICATION OF DMEPA'S DETERMINATION

On August 23, 2024, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

The proposed proprietary name, Avmapki, is conditionally acceptable.

3.1 COMMENTS TO VERASTEM

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

If any of the proposed product characteristics as stated in your submission, received on May 31, 2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

[e] POCA search conducted on July 3, 2024 in version 5.9.

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.[f]

*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 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.

[f] 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 ≥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[9]. 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-

[9] 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? *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? **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?		

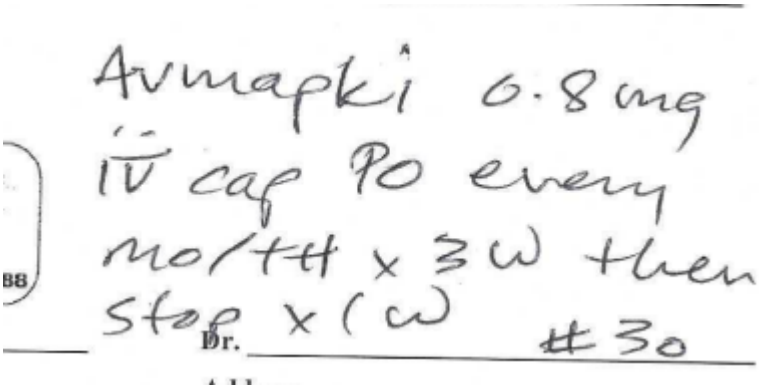
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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.
For single strength products, also consider circumstances where the strength may not be expressed.
For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.
To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:
• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.
• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
• Similar sounding doses: 15 mg is similar in sound to 50 mg</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)
• Do the names begin with different first letters?
• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
• *FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• 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? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

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. Avmapki Study (Conducted on 6/7/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: Avmapki Take (b) (4) cap PO once	Avmapki Take (b) (4) capsules by mouth on Mondays and Thursdays for 3 weeks then stop for 1 week. Dispense #30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Avmapki	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Avmapki People Received Study: 196 People Responded: 90					
Total	20	28	20	22	90
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ABMAPKEE	0	0	1	0	1
ABMAPKEY	0	0	1	0	1
ABMAVKEE	0	0	1	0	1
AFMAPQUE CAPSULES	0	0	1	0	1
ARMACQUI	0	0	1	0	1
ARMAPHI	2	0	0	0	2
ARMAPKI	7	0	0	0	7
AVAMPKI	0	1	0	0	1
AVMABKY	0	0	1	0	1
AVMAKI	0	0	1	0	1
AVMAPKE	0	0	1	0	1
AVMAPKEE	0	0	1	0	1
AVMAPKEY	0	0	4	0	4
AVMAPKI	5	26	3	22	56
AVMAPKY	0	0	1	0	1
AVMAPLI	0	1	0	0	1
AVMAPQI	0	0	1	0	1
AVMATKEE	0	0	1	0	1
AVMATKEY	0	0	1	0	1
AVMOPHI	1	0	0	0	1
CIMOPKI	1	0	0	0	1
CUMAPKI	3	0	0	0	3
CUMOPHI	1	0	0	0	1

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

No.	Proposed name: Avmapki Pronunciation: av map' kee Established name: avutometinib Dosage form: capsules Strength(s): 0.8 mg Dosage: (b) (4) mg ((b) (4) capsules) 2 times weekly for 3 weeks, followed by 1 week rest period, in each 4-week (28 day) cycle.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
	N/A		

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 (%)
	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: Avmapki Pronunciation: av map' kee Established name: avutometinib Dosage form: capsules Strength(s): 0.8 mg Dosage: (b) (4) mg ((b) (4) capsules) 2 times weekly for 3 weeks, followed by 1 week rest period, in each 4-week (28 day) cycle.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
	N/A		

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

No.	Name	POCA Score (%)
	N/A	

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
	N/A		

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

No.	Name	POCA Score (%)
	N/A	

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

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/s/

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