

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761126Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	July 3, 2023
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-txid) injection 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Tanvez BioPharma USA, Inc. (Tanvex)
Nexus NPNS ID #:	2023-117
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed four-letter suffix, -txid, for BLA 761126, which was found conditionally acceptable on May 30, 2019^a, January 22, 2021^b, and January 20, 2022^c for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761126.

1.1 Regulatory History

- We found the proposed four-letter suffix, -txid, conditionally acceptable for BLA 761126 on May 30, 2019^a.
- BLA 761126 received a Complete Response (CR) letter on September 24, 2019^d.
- Tanvex submitted a Class 2 Resubmission on November 20, 2020.
- We found the proposed suffix, -txid, conditionally acceptable upon re-review on January 22, 2021^b.
- BLA 761126 received a Complete Response (CR) letter on May 20, 2021^e.
- Tanvex submitted a Class 2 Resubmission on August 15, 2022.
- We found the proposed suffix, -txid, conditionally acceptable upon re-review on January 20, 2023^c.
- BLA 761126 received a Complete Response (CR) letter on February 14, 2023^f.
- Tanvex submitted a Class 2 Resubmission on April 24, 2023.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 May 30. RCM No.: 2019-774.

^b Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jan 20. RCM No.: 2019-774-1.

^c Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 Jan 20. Nexus NPNS ID No.: 2022-151

^d Deisseroth, A. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2019 Sep 24.

^e Deisseroth, A. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2021 May 20.

^f Wroblewski, T.M. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2023 Feb 14.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously conditionally acceptable four-letter suffix, -txid, using the principles described in the applicable guidance^a.

We determined that the proposed suffix -txid, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. In email correspondence dated August 2, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on August 3, 2023.

4 CONCLUSION

We find the suffix -txid acceptable and recommend the nonproprietary name filgrastim-txid be used throughout the labels and labeling.

^a Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

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/s/

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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 27, 2023
Application Type and Number:	BLA 761126
Product Name and Strength:	TX01 ^a Nypozi (filgrastim-txid) ^b Injection, 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Tanvex BioPharma USA, Inc. (Tanvex)
PNR ID #:	2023-1044725116
DMEPA 2 Safety Evaluator:	Sue Black, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

^a TX01 has been developed as a proposed biosimilar to US-licensed Neupogen (filgrastim).

^b The nonproprietary name, filgrastim-txid, was found conditionally acceptable on January 20, 2023 and is currently under re-review.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nypozi, which was found conditionally acceptable under BLA 761126 on October 18, 2022. Thus, Tanvex submitted the name, Nypozi, under BLA 761126 for review on April 24, 2023. Tanvex submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external study was previously reviewed under BLA 761126 (see Section 1.1 below).

We note that all product characteristics remain the same.

1.1 REGULATORY HISTORY

Tanvex previously submitted the proposed proprietary name, (b) (4)***, to IND 113556 on November 21, 2017.^c However, the Office of Prescription Drug Promotion (OPDP) found the name unacceptable on April 3, 2018.^d Subsequently, Tanvex submitted the proposed proprietary name, (b) (4)***, to IND 113556 on May 15, 2018.^e However, Tanvex withdrew the proposed name (b) (4)*** on September 20, 2018.^f

Under BLA 761126, the Applicant then submitted the proposed proprietary name, Nypozi, on September 28, 2018. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Nypozi acceptable.^g However, the Division of Hematology Products (DHP) issued a Complete Response (CR) for the application on September 24, 2019. The Applicant resubmitted the application and the proposed proprietary name, Nypozi, for review on November 20, 2020. Subsequently, the proposed proprietary name was found conditionally acceptable on February 10, 2021.^h However, the Division of Non-Malignant Hematology (DNH) issued a Complete Response (CR) for the application on May 20, 2021.

On August 15, 2022, the Applicant resubmitted the application and the proposed proprietary name, Nypozi, for review under BLA 761126. Subsequently, the proposed proprietary name was found conditionally acceptable on October 18, 2022.ⁱ However, the Division of Non-Malignant Hematology (DNH) issued a Complete Response (CR) for the application on February 14, 2023.

^c Cover Letter - Request for Review of Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 21 NOV 2017. Available from: <\\cdsesub1\evsprod\ind113556\0022\m1\us\12-cover-letters\2017-11-20-cover-letter-sn-0022.pdf>

^d Rahimi, L. Proprietary Name Review for (b) (4)*** (IND 113556). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 APR 03. Panorama No. 2017-19173699.

^e Cover Letter - Request for Review of Proposed Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 15 MAY 2018. Available from: <\\cdsesub1\evsprod\ind113556\0028\m1\us\12-cover-letters\2018-05-09-cover-letter-sn-0028.pdf>

^f Cover Letter – Withdrawal of Request for Proprietary Name Review for IND 113556. Irvine (CA). Tanvex BioPharma USA; 20 SEP 2018. Available from: <\\CDSESUB1\EVSPROD\ind113556\0030\m1\us\12-cover-letters\2018-09-20-cover-letter-sn-0030.pdf>

^g Mena-Grillasca, C. Proprietary Name Review for Nypozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 NOV 30. RCM No.: 2018-26291716.

^h Straka, M. Proprietary Name Review for Nyozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 10. RCM No.: 2020-44032462.

ⁱ Kane, D. Proprietary Name Review for Nypozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 OCT 18. PNR ID No. 2022-1044724709.

On April 24, 2023, Tanvex resubmitted BLA 761126 and the proposed proprietary name, Nypozi for review under BLA 761126.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nypozi 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 Nypozi. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Nypozi.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The June 1, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Nypozi.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On June 27, 2023, we communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

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

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO TANVEX BIOPHARMA USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 24, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

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SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	January 20, 2022
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-txid) injection 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Tanvez BioPharma USA, Inc. (Tanvex)
Nexus NPNS ID #:	2022-151
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed four-letter suffix, -txid, for BLA 761126, which was found conditionally acceptable on May 30, 2019^a and January 22, 2021^b for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761126.

1.1 Regulatory History

- We found the proposed four-letter suffix, -txid, conditionally acceptable for BLA 761126 on May 30, 2019^a.
- BLA 761126 received a Complete Response (CR) letter on September 24, 2019^c.
- Tanvex submitted a Class 2 Resubmission on November 20, 2020.
- We found the proposed suffix, -txid, conditionally acceptable upon re-review on January 22, 2021^b.
- BLA 761126 received a Complete Response (CR) letter on May 20, 2021^d.
- Tanvex submitted a Class 2 Resubmission on August 15, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously conditionally acceptable four-letter suffix, -txid, using the principles described in the applicable guidance^e.

We determined that the FDA-generated suffix -txid, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 May 30. RCM No.: 2019-774.

^b Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jan 20. RCM No.: 2019-774-1.

^c Deisseroth, A. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2019 Sep 24.

^d Deisseroth, A. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2021 May 20.

^e Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. In email correspondence dated January 19, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. However, OPDP noted that the suffix -txid include the abbreviations 'tx' for treatment and 'id' for identification. DMEPA had formerly identified and evaluated the inclusion of these abbreviations in a previous review^b and found it acceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on January 20, 2023.

4 CONCLUSION

We find the suffix -txid acceptable and recommend the nonproprietary name filgrastim-txid be used throughout the labels and labeling.

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/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)

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Date of This Review:	October 18, 2022
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-txid) ^a Injection, 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Tanvex BioPharma USA, Inc. (Tanvex)
PNR ID #:	2022-1044724709
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

^a BLA 761126 has been developed as a proposed biosimilar to US-licensed Neupogen (filgrastim). The nonproprietary name “filgrastim-txid” has been found conditionally acceptable for this BLA on January 22, 2021.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nypozi, 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. Tanvex submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external study was previously reviewed under BLA 761126 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Tanvex previously submitted the proposed proprietary name, (b) (4)***, to IND 113556 on November 21, 2017.^b However, the Office of Prescription Drug Promotion (OPDP) found the name unacceptable on April 3, 2018.^c Subsequently, Tanvex submitted the proposed proprietary name, (b) (4)***, to IND 113556 on May 15, 2018.^d However, Tanvex withdrew the proposed name (b) (4)*** on September 20, 2018.^e

Under BLA 761126, the Applicant then submitted the proposed proprietary name, Nypozi, on September 28, 2018. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Nypozi*** acceptable.^f However, the Division of Hematology Products (DHP) issued a Complete Response (CR) for the application on September 24, 2019. The Applicant resubmitted the application and the proposed proprietary name, Nypozi, for review on November 20, 2020. Subsequently, the proposed proprietary name was found conditionally acceptable on February 12, 2021.^g However, the Division of Non-Malignant Hematology (DNH) issued a Complete Response (CR) for the application on May 20, 2021.

On August 15, 2022, the Applicant resubmitted the application and the proposed proprietary name, Nypozi, for review under BLA 761126.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 15, 2022.

^b Cover Letter - Request for Review of Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 21 NOV 2017. Available from: <\\cdsesub1\evsprod\ind113556\0022\m1\us\12-cover-letters\2017-11-20-coverletter-sn-0022.pdf>

^c Rahimi, L. Proprietary Name Review for (b) (4)*** (IND 113556). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 APR 03. Panorama No. 2017-19173699.

^d Cover Letter - Request for Review of Proposed Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 15 MAY 2018. Available from: <\\cdsesub1\evsprod\ind113556\0028\m1\us\12-cover-letters\2018-05-09-cover-letter-sn-0028.pdf>

^e Cover Letter – Withdrawal of Request for Proprietary Name Review for IND 113556. Irvine (CA). Tanvex BioPharma USA; 20 SEP 2018.

^f Mena-Grillasca, C. Proprietary Name Review for Nyozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 NOV 30. RCM No.: 2018-26291716.

^g Straka, M. Proprietary Name Review for Nyozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 10. RCM No.: 2020-44032462.

- Intended Pronunciation: nī PŌ zē
- Nonproprietary Name: filgrastim-txid^h
- Indication of Use: Leukocyte growth factor indicated to:
 - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
 - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
 - Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
 - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
 - Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)
- Route of Administration: Subcutaneous, Intravenous
- Dosage Form: Injection
- Strength: 300 mcg/0.5 mL and 480 mcg/0.8 mL
- Dose and Frequency:
 - Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion. See Full Prescribing Information for recommended dosage adjustments and timing of administration
 - Patients with cancer undergoing bone marrow transplantation
 - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. See Full Prescribing Information for recommended dosage adjustments and timing of administration

^h Mena-Grillasca, C. Nonproprietary Name Suffix Review for Nypozi (filgrastim-txid) (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JAN 22. RCM No.: 2019-774-1.

- Patients undergoing autologous peripheral blood progenitor cell collection and therapy
 - 10 mcg/kg/day subcutaneous injection
 - Administer for at least 4 days before first leukapheresis procedure and continue until last leukapheresis procedure
- Patients with congenital neutropenia
 - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily
- Patients with cyclic or idiopathic neutropenia
 - Recommended starting dose is 5 mcg/kg subcutaneous injection daily
- Direct administration of less than 0.3 mL is not recommended due to potential for dosing errors
- How Supplied: Pack of 1 prefilled syringe, Pack of 10 prefilled syringes
- Storage: 2°C to 8°C (36°F to 46°F)
- Reference Listed Drug/Reference Product: Neupogen, BLA 103353

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nypozi 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 Nypozi. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Nypozi.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary nameⁱ.

2.2.2 *Components of the Proposed Proprietary Name*

Tanvex did not provide a derivation or intended meaning for the proposed proprietary name, Nypozi, in their submission. This proprietary name is comprised of a single word. We note that the proposed name Nypozi contain the letters 'po', which is the abbreviation for 'by mouth' or

ⁱ USAN stem search conducted on September 23, 2022.

‘orally’. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the letter string ‘po’ positioned in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Nypozi that does not contain any additional components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On September 29, 2022, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Nypozi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred (100) practitioners participated in DMEPA’s prescription studies for Nypozi.

In the computerized provider order entry (CPOE) study, one participant entered an incorrect sequence of letters, ‘pos’ instead of ‘nyp’, when searching for the study name. After 11 seconds passed, the participant incorrectly selected the first name on the list ‘Adipost’, suggesting that the participant selected a random name in order to proceed with the simulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. We evaluate this name pair in Appendix F.

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^j identified 17 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. 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. Therefore, we identified 0 names not previously analyzed.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our prescription simulation study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names

^j POCA search conducted on August 31, 2022 in version 4.4.

Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	0
Low similarity name pair: combined match percentage score $\leq 54\%$	1

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 1 name contained in Table 1 determined it will not pose a risk for confusion with Nypozi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On October 18, 2022, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Nypozi, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO TANVEX BIOPHARMA USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 15, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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 http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

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>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^k

^k National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. 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, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Table 3-5) 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 3).
- 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 names¹. 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 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) 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

¹ Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 staff also conducts a prescription simulation studies using FDA health care professionals.

Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as 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 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

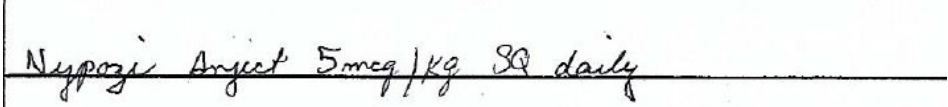
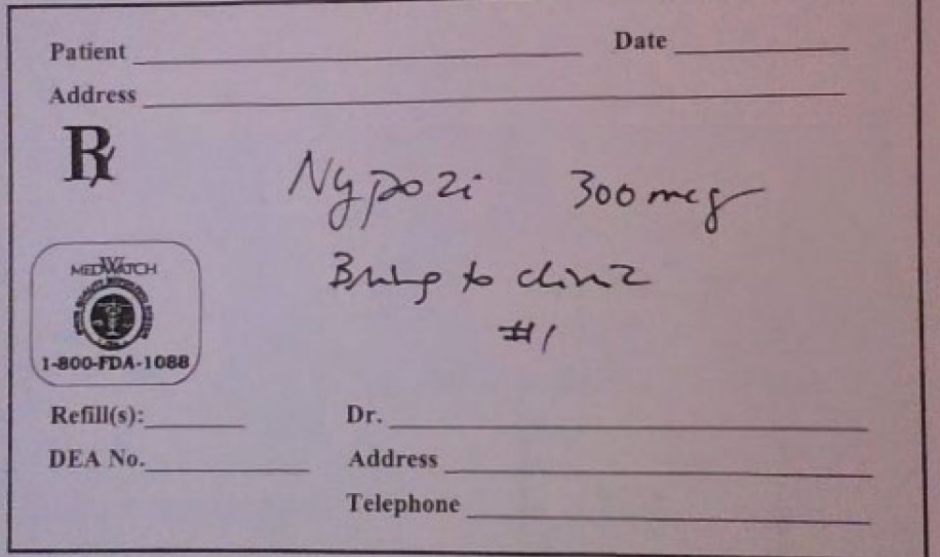
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 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?	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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Nypozi Study (Conducted on September 9, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Nypozi 300 mcg Bring to Clinic #1
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Nypozi	

FDA Prescription Simulation Responses (Aggregate Report)

265 People Received Study
100 People Responded

Study Name: Nypozi

Total	24	22	28	26	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
ADIPOST	0	1	0	0	1
HYPOZI	0	0	0	1	1
LYPOSE	0	0	1	0	1
LYPOZI	0	0	1	0	1
MIPOZE	0	0	1	0	1
MYPOGI	0	0	1	0	1
MYPOSI	0	0	1	0	1
MYPOSIE	0	0	1	0	1
MYPOSY	0	0	2	0	2
MYPOZI	0	0	2	0	2
MYPOZY	0	0	1	0	1
NIGHPOZI 300MG	0	0	1	0	1
NIPOZI	0	0	3	0	3
NYPOSEY	0	0	2	0	2
NYPOSI	0	0	2	0	2
NYPOSIE	0	0	1	0	1
NYPOSY	0	0	1	0	1
NYPOZI	22	21	3	25	71
NYPOZI INJECTION	1	0	0	0	1
NYPOZY	0	0	3	0	3
NYPROZI	1	0	0	0	1
ZYPOZY	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$) – N/A

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose - N/A

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Adipost	42

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described. – N/A

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^m. – N/A

^m 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

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/

DEVIN R KANE
10/18/2022 02:38:31 PM

HINA S MEHTA
10/18/2022 04:23:29 PM

CHI-MING TU
10/19/2022 09:14:01 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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:	February 10, 2021
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (Filgrastim-txid) ^a Injection, 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Tanvex BioPharma USA, Inc. (Tanvex)
Panorama #:	2020-44032462
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Hina Mehta, PharmD

^a BLA 761126 has been developed as a proposed biosimilar to US-licensed Neupogen (filgrastim). The nonproprietary name “filgrastim-txid” has been found conditionally acceptable for this BLA on January 22, 2021.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nypozi, 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. Tanvex submitted an external name study, conducted by (b) (4), for this proposed proprietary name which was evaluated in the previous review.

1.1 REGULATORY HISTORY

Tanvex previously submitted the proposed proprietary name, (b) (4)***, to IND 113556 on November 21, 2017^b. However, the Office of Prescription Drug Promotion (OPDP) found the name unacceptable on April 3, 2018^c. Subsequently, Tanvex submitted the proposed proprietary name, (b) (4)***, to IND 113556 on May 15, 2018^d. However, Tanvex withdrew the proposed name (b) (4)*** on September 20, 2018^e.

The Applicant then submitted the proposed proprietary name, Nypozi, on September 18, 2018. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Nypozi*** acceptable.^f However, the Division of Hematology Products (DHP) issued a Complete Response (CR) for the application on September 24, 2019. The Applicant re-submitted the application and the proposed proprietary name, Nypozi, for review on November 20, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 20, 2020.

- Intended Pronunciation: nī PŌ zē
- Nonproprietary Name: Filgrastim-txid^g

^b Cover Letter - Request for Review of Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 21 NOV 2017. Available from: <\\cdsesub1\evsprod\ind113556\0022\m1\us\12-cover-letters\2017-11-20-cover-letter-sn-0022.pdf>

^c Rahimi, L. Proprietary Name Review for (b) (4)*** (IND 113556)). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 APR 03. Panorama No. 2017-19173699.

^d Cover Letter - Request for Review of Proposed Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 15 MAY 2018. Available from: <\\cdsesub1\evsprod\ind113556\0028\m1\us\12-cover-letters\2018-05-09-cover-letter-sn-0028.pdf>

^e Cover Letter – Withdrawal of Request for Proprietary Name Review for IND 113556. Irvine (CA). Tanvex BioPharma USA; 20 SEP 2018.

^f Mena-Grillasca, C. Proprietary Name Review for Nyozi (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 NOV 30. RCM No.: 2018-26291716.

^g Mena-Grillasca, C. Nonproprietary Name Suffix Review for Nypozi (filgrastim-txid) (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JAN 22. RCM No.: 2019-774-1.

- Indication of Use:
 - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
 - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
 - Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
 - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- Route of Administration: Subcutaneous, Intravenous
- Dosage Form: Injection
- Strength: 300 mcg/0.5 mL and 480 mcg/0.8 mL
- Dose and Frequency:
 - Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion. See Full Prescribing Information for recommended dosage adjustments and timing of administration
 - Patients with cancer undergoing bone marrow transplantation
 - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. See Full Prescribing Information for recommended dosage adjustments and timing of administration
 - Patients undergoing autologous peripheral blood progenitor cell collection and therapy
 - 10 mcg/kg/day subcutaneous injection
 - Administer for at least 4 days before first leukapheresis procedure and continue until last leukapheresis procedure
 - Patients with congenital neutropenia
 - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily

- Patients with cyclic or idiopathic neutropenia
 - Recommended starting dose is 5 mcg/kg subcutaneous injection daily
- Direct administration of less than 0.3 mL is not recommended due to potential for dosing errors
- How Supplied: Pack of 1 prefilled syringe, Pack of 10 prefilled syringes
- Storage: 2°C to 8°C (36°F to 46°F)
- Reference Product: Neupogen (BLA 103353)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nypozi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Nypozi.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^h.

2.2.2 *Components of the Proposed Proprietary Name*

Tanvex did not provide a derivation or intended meaning for the proposed proprietary name, Nypozi, in their submission. This proprietary name is comprised of a single word. We note that the proposed name Nypozi contain the letters 'po', which is the abbreviation for 'by mouth' or 'orally'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the letter string 'po' positioned in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Nypozi that does not contain any additional components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

^h USAN stem search conducted on January 22, 2021.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 15, 2020 e-mail, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Nypozi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-one (71) practitioners participated in DMEPA's prescription studies for Nypozi. 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 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA searchⁱ identified 17 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. 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. Therefore, we identified 3 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	1

ⁱ POCA search conducted on January 22, 2021 in version 4.4.

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 3 names contained in Table 1 determined none of the names will pose a risk for confusion with Nypozi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on February 5, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Non-Malignant Hematology (DNH) on February 9, 2021, they stated no additional concerns with the proposed proprietary name, Nypozi.

3 CONCLUSION

The proposed proprietary name, Nypozi, is acceptable.

If you have any questions or need clarifications, please contact Linda Park, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO TANVEX BIOPHARMA USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 20, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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 http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

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>).

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1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^j

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. 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, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Table 3-5) 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 3).
- 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^k. 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 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) 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

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

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 staff also conducts a prescription simulation studies using FDA health care professionals.

Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

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

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as 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 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

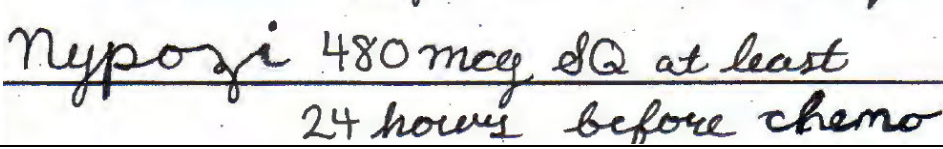
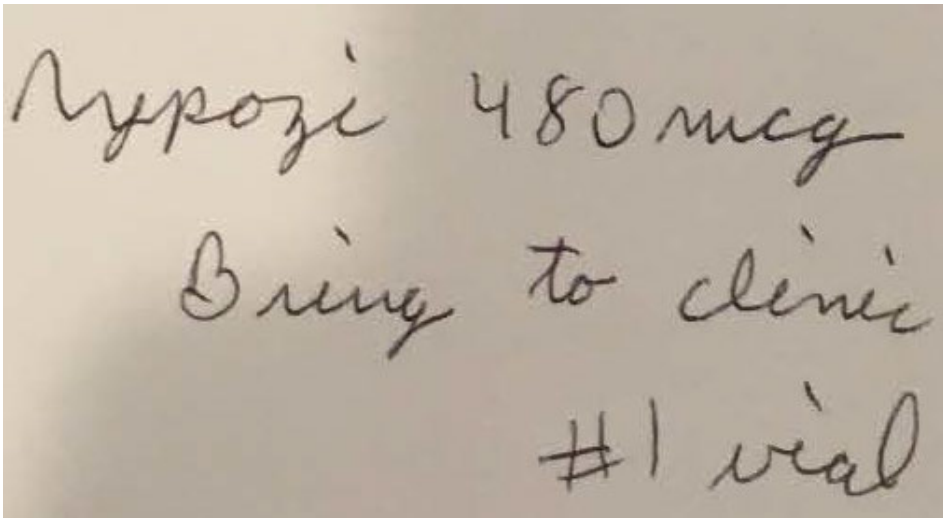
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 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?	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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Nypozi Study (Conducted on January 5, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u>  Nypozi 480 mcg SQ at least 24 hours before chemo	Nypozi Bring to clinic #1 vial
<u>Outpatient Prescription:</u>  Nypozi 480 mcg Bring to clinic #1 vial	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Nypozi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Nypozi

As of Date 1/22/2021

209 People Received Study
71 People Responded

Study Name: Nypozi

Total	21	15	21	14	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
MYPOZIC	1	0	0	0	1
NIPOLZI	0	0	1	0	1
NIPOSEY	0	0	1	0	1
NIPOZI	0	0	2	0	2
NIPOZY	0	0	3	0	3
NIPULZY	0	0	1	0	1
NITOPOSI 480 MG	0	0	1	0	1
NYCOVIL	0	0	1	0	1
NYPOLDINE	0	0	1	0	1
NYPOLSY	0	0	1	0	1
NYPOSI	0	0	1	0	1
NYPOSY	0	0	2	0	2
NYPOZEE	0	0	1	0	1
NYPOZI	10	15	3	14	42
NYPOZY	0	0	2	0	2
NYPROZI	1	0	0	0	1
RYPOZI	6	0	0	0	6
VYPOZI	1	0	0	0	1
1XYPOZI	1	0	0	0	1
ZYPOZI	1	0	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Nypozi Established name: Filgrastim-txid Dosage form: Injection Strength(s): 300 mcg/0.5 mL and 480 mcg/0.8 mL Usual Dose: 5 mcg/kg/day, 6 mcg/kg, or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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 $\geq 55\%$ to $\leq 69\%$) 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 $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Nypozi Established name: Filgrastim-txid Dosage form: Injection Strength(s): 300 mcg/0.5 mL and 480 mcg/0.8 mL Usual Dose: 5 mcg/kg/day, 6 mcg/kg, or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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 $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Tepezza	52

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	55	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) dated (b) (4)). Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable for NDA (b) (4).

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion¹.

No.	Name	POCA Score (%)
1.	(b) (4) ***	55

¹ 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/

MAXIMILIAN STRAKA
02/10/2021 11:34:48 AM

HINA S MEHTA
02/11/2021 10:26:16 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	January 22, 2021
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-txid) injection 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Tanzev BioPharma USA, Inc. (Tanvex)
OSE RCM #:	2019-774-1
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed four-letter suffix, -txid, for BLA 761126, which was found conditionally acceptable on May 30, 2019^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761126.

1.1 Regulatory History

FDA found the proposed four-letter suffix, -txid, conditionally acceptable for BLA 761126 on May 30, 2019^a. However, BLA 761126 received a Complete Response (CR) letter on September 24, 2019^b. Thus, Tanvex submitted a Class 2 Resubmission on November 20, 2020.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously conditionally acceptable four-letter suffix, -txid, using the principles described in the applicable guidance^c.

The proposed suffix -txid is comprised of 4 distinct letters. We note that the letters 'tx' and 'id' in the suffix represent the medical abbreviations for 'treatment' and 'identification', respectively. We considered whether the inclusion of the letters 'tx' and 'id' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -txid, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for filgrastim-txid (BLA 761126). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 May 30. RCM No.: 2019-774.

^b Deisseroth, A. Complete Response (BLA 761126). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2019 Sep 24.

^c See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated January 13, 2021, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on January 15, 2021.

4 CONCLUSION

We find the suffix -txid acceptable. Should the 351(k) BLA be approved during this review cycle, filgrastim-txid will be the proper name designated in the license.

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/s/

CARLOS M MENA-GRILLASCA
01/22/2021 10:35:37 AM

DANIELLE M HARRIS
01/22/2021 02:47:40 PM

MEMORANDUM
SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)
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 30, 2019
Responsible OND Division:	Division of Hematology Products (DHP)
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-txid) injection 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Drug-Biologic)
Applicant/Sponsor Name:	Tanvex BioPharma USA, Inc. (Tanvex)
FDA Received Date:	September 28, 2018
OSE RCM #:	2019-774
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Tanvex for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761126.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On September 28, 2018, Tanvex submitted a list of 8 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Table 1 presents a list of suffixes submitted by Tanvex:

Table 1. Suffixes submitted by Tanvex***	
1.	txid
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	

We reviewed Tanvex's proposed suffixes in the order of preference listed by Tanvex, using the principles described in the applicable guidance.^b

2.1 filgrastim-txid

Tanvex's first proposed suffix, -txid, is composed of four distinct letters.

We determined that the proposed suffix -txid, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated May 29, 2019, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Hematology Products (DHP) via e-mail on May 30, 2019.

4 CONCLUSION

We find Tanvex's proposed suffix -txid acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to filgrastim-txid. DMEPA will communicate our findings to the Applicant via letter.

^a Request for Review of Proprietary Name (BLA 761126). Irvine (CA): Tanvex BioPharma USA, Inc.; 2018 Sep 28. Available at: <\\cdsesub1\evsprod\bla761126\0001\m1\us\118-proprietary-names\1-18-request-for-review-of-proprietary-name.pdf>

^b See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

4.1 Recommendations for Tanvex BioPharma USA, Inc.

We find the nonproprietary name, filgrastim-txid, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, filgrastim-txid will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/

CARLOS M MENA-GRILLASCA
05/30/2019 05:20:35 PM

DANIELLE M HARRIS
05/31/2019 08:53:39 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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:	November 30, 2018
Application Type and Number:	BLA 761126
Product Name and Strength:	Nypozi (filgrastim-xxxx) ^a Injection 300 mcg/0.5 mL and 480 mcg/0.8 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Tanvex BioPharma USA, Inc. (Tanvex)
Panorama #:	2018-26291716
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

^a BLA 761126 has been developed as a proposed biosimilar to US-licensed Neulasta (filgrastim). Since the nonproprietary name for BLA 761126 has not been determined, the nonproprietary name placeholder (filgrastim-xxxx) is used throughout this review.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nypozi, 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. Tanvex submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

Tanvex previously submitted the proposed proprietary name, (b) (4)***, to IND 113556 on November 21, 2017^b. However, the Office of Prescription Drug Promotion (OPDP) found the name unacceptable on April 3, 2018^c. Subsequently, Tanvex submitted the proposed proprietary name, (b) (4)***, to IND 113556 on May 15, 2018^d. However, Tanvex withdrew the proposed name (b) (4)*** on September 20, 2018^e.

Thus, Tanvex submitted the proposed name, Nypozi, for review on September 18, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 18, 2018.

- Intended Pronunciation: nī PŌ zē
- Active Ingredient: filgrastim-xxxx^f
- Indication of Use:
 - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
 - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
 - Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
 - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

^b Cover Letter - Request for Review of Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 21 NOV 2017. Available from: <\\cdsesub1\evsprod\ind113556\0022\m1\us\12-cover-letters\2017-11-20-cover-letter-sn-0022.pdf>

^c Rahimi, L. Proprietary Name Review for (b) (4)*** (IND 113556)). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 APR 03. Panorama No. 2017-19173699.

^d Cover Letter - Request for Review of Proposed Proprietary Name for IND 113556. Irvine (CA). Tanvex BioPharma USA; 15 MAY 2018. Available from: <\\cdsesub1\evsprod\ind113556\0028\m1\us\12-cover-letters\2018-05-09-cover-letter-sn-0028.pdf>

^e Cover Letter – Withdrawal of Request for Proprietary Name Review for IND 113556. Irvine (CA). Tanvex BioPharma USA; 20 SEP 2018.

^f BLA 761126 has been developed as a proposed biosimilar to US-licensed Neulasta (filgrastim). Since the nonproprietary name for BLA 761126 has not been determined, the nonproprietary name placeholder (filgrastim-xxxx) is used throughout this review

- Route of Administration: Subcutaneous, Intravenous
- Dosage Form: Injection
- Strength: 300 mcg/0.5 mL and 480 mcg/0.8 mL
- Dose and Frequency:
 - Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion. See Full Prescribing Information for recommended dosage adjustments and timing of administration
 - Patients with cancer undergoing bone marrow transplantation
 - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. See Full Prescribing Information for recommended dosage adjustments and timing of administration
 - Patients undergoing autologous peripheral blood progenitor cell collection and therapy
 - 10 mcg/kg/day subcutaneous injection
 - Administer for at least 4 days before first leukapheresis procedure and continue until last leukapheresis procedure
 - Patients with congenital neutropenia
 - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily
 - Patients with cyclic or idiopathic neutropenia
 - Recommended starting dose is 5 mcg/kg subcutaneous injection daily
 - Direct administration of less than 0.3 mL is not recommended due to potential for dosing errors
- How Supplied: Pack of 1 prefilled syringe, Pack of 10 prefilled syringes
- Storage: 2°C to 8°C (36°F to 46°F)
- Reference Listed Drug/Reference Product: Neupogen BLA 103353

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name⁹.

2.2.2 Components of the Proposed Proprietary Name

Tanvex did not provide a derivation or intended meaning for the proposed proprietary name, Nypozi, in their submission. This proprietary name is comprised of a single word. We note that the proposed name Nypozi

⁹ USAN stem search conducted on November 19, 2018.

contain the letters 'po', which is the abbreviation for 'by mouth' or 'orally'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the letter string 'po' positioned in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Nypozi that does not contain any additional components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 17, 2018 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to Nypozi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Forty-five practitioners participated in DMEPA's prescription studies for Nypozi. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^h identified 14 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4). These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	13
Low similarity name pair: combined match percentage score $\leq 54\%$	0

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 15 names contained in Table 1 determined none of the names will pose a risk for confusion with Nypozi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on November 29, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-

^h POCA search conducted on November 14, 2018 in version 4.2.

mail correspondence from the Division of Hematology Products (DHP) on November 29, 2018, they stated no additional concerns with the proposed proprietary name, Nypozi.

3 CONCLUSION

The proposed proprietary name, Nypozi, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO TANVEX BIOPHARMA USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 18, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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 http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

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#>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. 6F

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. 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, CernerRxNorm, 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:

[†] National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Table 3-5) 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 3).
- 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^{7f}. 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 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) 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 staff also conducts a prescription simulation studies using FDA health care professionals.

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

^{7f} Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq 70\%$).

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and ħ, 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 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses. <table border="1" data-bbox="284 957 1346 1568"> <thead> <tr> <th data-bbox="284 957 868 993">Orthographic Checklist (Y/N to each question)</th><th data-bbox="868 957 1346 993">Phonetic Checklist (Y/N to each question)</th></tr> </thead> <tbody> <tr> <td data-bbox="284 993 868 1568"> • 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 ħ, is 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? </td><td data-bbox="868 993 1346 1568"> • 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> </tbody> </table>	Orthographic Checklist (Y/N to each question)	Phonetic 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 ħ, is 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?	• 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?
Orthographic Checklist (Y/N to each question)	Phonetic 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 ħ, is 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?	• 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: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Nypozi Study (Conducted on October 25, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Nypozi 480mcg SQ at least 24hrs before chemo</i>	Nypozi 480 mcg Bring to clinic. Dispense 1 vial
<u>Outpatient Prescription:</u> <i>Nypozi 480mcg</i> <i>bring to clinic</i> <i>#1 vial</i>	

FDA Prescription Simulation Responses (Aggregate Report)

As of Date 11/20/2018

306 People Received Study
45 People Responded

Study Name: Nypozi

Total	18	10	17	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
MYPOZI	0	0	1	1
NEIPOSEY	0	1	0	1
NIGHTPOSI 480 MG	0	1	0	1
NIPOSEY	0	1	0	1
NIPOSI	0	2	0	2
NIPOZI	0	2	0	2
NUPOZI SQ	0	0	1	1
NYPAZI	0	0	2	2
NYPOPZI	0	0	1	1
NYPOSI	0	1	0	1
NYPOSIE	0	1	0	1
NYPOSZE	0	1	0	1
NYPOZI	18	0	12	30

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Nypozi Established name: filgrastim-xxxx ^k Dosage form: Injection Strength(s): 300 mcg/0.5 mL and 480 mcg/0.8 mL Usual Dose: 5 mcg/kg/day, 6 mcg/kg, or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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.
1.	Nypozi	100	Name is the subject of this review.
2.	Nypozin	88	Name identified by (b) (4) Line of over-the-counter topical and oral natural health products for joint and muscle pain available in Sweden. Product not identified in any United States drug databases.

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
3.	NoDoz	60
4.	Nytol	60
5.	Nystop	56
6.	Mytesi	56

^k BLA 761126 has been developed as a proposed biosimilar to US-licensed Neulasta (filgrastim). Since the nonproprietary name for BLA 761126 has not been determined, the nonproprietary name placeholder (filgrastim-xxxx) is used throughout this review

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Nypozi Established name: filgrastim-xxxx ¹ Dosage form: Injection Strength(s): 300 mcg/0.5 mL and 480 mcg/0.8 mL Usual Dose: 5 mcg/kg/day, 6 mcg/kg, or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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
7.	(b) (4) *** (Intended pronunciation: (b) (4))	64	(b) (4)

¹ BLA 761126 has been developed as a proposed biosimilar to US-licensed Neulasta (filgrastim). Since the nonproprietary name for BLA 761126 has not been determined, the nonproprietary name placeholder (filgrastim-xxxx) is used throughout this review

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

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
8.	Niconil	56	Discontinued international nicotine product formerly marketed in the UK and Ireland.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^m.

No.	Name	POCA Score (%)
9.	Impoyz	58
10.	Inqovi***	58
11.	Xpovio***	58
12.	Deponit	56
13.	Pitocin	56
14.	Zeposia***	56
15.	Zytopic	56

^m 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

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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11/30/2018

HINA S MEHTA
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