CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761373Orig1s000
761425Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum

From:

Carlos M Mena-Grillasca, BS Pharm
Biologics Suffix Specialist
Division of Medication Error Prevention and Analysys I
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Carlos Mena-grillasca -S
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Through:

Mishale Mistry, PharmD, MPH
Director, Division of Medication Error Prevention and Analysis I
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
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Gerald Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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Date: 2024.06.04 13:31:51 -04'00'

Subject: Evaluation of the nonproprietary name for BLA 761425

Samsung Bioepis Co., Ltd. (Samsung) submitted two Biologics License Applications (BLA 761373 and BLA 761425) pursuant to Section 351(k) of the Public Health Service Act as a proposed (b) (4) biosimilar to the reference product Stelara (ustekinumab) on March 30, 2023, and January 29, 2024, respectively.

BLA 761373 was submitted to the Division of Dermatology and Dentistry (DDD) for the 45 mg/0.5 mL and 90 mg/mL pre-filled syringe presentations used for the subcutaneous administration of ustekinumab-xxxx for all indications. BLA 761425 was submitted to the Division of Gastroenterology for the 130/26 mL (5 mg/mL) single-dose vial presentation used for the intravenous administration of ustekinumab-xxxx as the initial dose for the Crohn's disease and Ulcerative Colitis indications. We note that Samsung originally submitted all presentations (pre-filled syringe for subcutaneous administration and single-dose vial for intravenous administration) with BLA 761373. However, late in the review cycle, Samsung made the business decision to submit a separate 351(k) application for the 130 mg/26 mL intravenous vial presentation with the purpose of separating the BLA in the format similar to that of Stelara (ustekinumab) (BLA 125261 for the subcutaneous injection, and BLA 761044 for the intravenous vial). Also, since the subcutaneous and intravenous formulations for BLAs 761373 and 761425 are developed from a common drug substance, BLA 761425 cross-references BLA 761373. The BsUFA goal date to take action on BLA 761373 is June 30, 2024, and for BLA 761425 is January 29, 2025. However, OND plans to take action on both applications by June 30, 2024.

The proposed product is a human interleukin-12 and -23 antagonist. The proposed indications for BLA 761373 are (1) adult patients with: moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn's disease, and moderately to severely active ulcerative colitis and (2) pediatric patients 6 years and older with: moderately to severe plaque psoriasis and active psoriatic arthritis. The proposed indications for BLA 761425 are Crohn's disease and Ulcerative Colitis.

The formulation in BLA 761425 contains the same drug substance (DS) (ustekinumab-xxxx) as BLA 761373, formulated at a strength of 130 mg/26 mL (5 mg/mL) in a single-dose vial, intended for the same indications of Crohn's disease and Ulcerative Colitis (not for plaque psoriasis and psoriatic arthritis), and dosage form (injection). The formulation in BLA 761425 is for intravenous administration. See Appendix A– Product Characteristics Comparison Table for more information.

The ustekinumab-xxxx DS (b) (4) of the proposed vial presentation for intravenous administration is the same used for the prefilled syringe presentations for subcutaneous administration.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, stating the Agency's intention to designate proper names that include four-letter

distinguishing suffixes for biological products[a]. Both of these 351(k) applications are within the scope of this naming guidance.

As such, the proposed nonproprietary name suffix -ttwe was found conditionally acceptable[b] for BLA 761373, and if approved, the proper name designated in the license will be ustekinumab-ttwe. We carefully considered whether the nonproprietary name for BLA 761425 should include a different distinguishing suffix than that designated for BLA 761373 or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating the same proper name (i.e., ustekinumab-ttwe) for BLA 761425. Among the factors, we have considered are the following:

1. The DS in BLA 761373 is the same as the DS in BLA 761425 and they are essentially unchanged with respect to product quality attributes (identity, strength, quality, purity, and/or potency.). The main differences between the formulations are the total strength, concentration, dose, route, and frequency of administration.
2. Considering that BLA 761373 and BLA 761425 share the same DS and formulation similarities, no significant differences in immunogenicity profiles are expected.
3. We note that other product characteristics are the same or similar. The two indications for BLA 761425 (Crohn's disease and ulcerative colitis) are also among the indications for BLA 761373 (plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis). The dosage form for both BLAs are injection. BLA 761425 is administered by intravenous injection once as a loading dose for Crohn's disease and ulcerative colitis, then the patient continues maintenance treatment with the subcutaneous injection from BLA 761373. BLA 761373 is administered by subcutaneous injection for the treatment of plaque psoriasis and psoriatic arthritis. See Appendix A.
4. We note above that Samsung originally submitted both formulations (subcutaneous and intravenous) in a single BLA, but subsequently made the business decision to split the BLA to follow a format similar to the Reference Product US-licensed Stelara.
5. Furthermore, a precedent was established with the approval of Wezlana (ustekinumab-auub) on October 31, 2023, the first interchangeable biosimilar to US-licensed Stelara. Wezlana was also submitted to the Agency as two separate BLAs (BLA 761331 and BLA 761285), following the format of the Reference Product US-licensed Stelara.

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[a] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "naming guidance").

[redacted] (b) (4)

6. Samsung is proposing to have the same proprietary name and U.S. prescribing information (USPI) for both BLAs. DMEPA 1 found the proposed name Pyzchiva conditionally acceptable on June 14, 2023[c] and April 26, 2024[d].
7. As noted in the final Nonproprietary Naming of Biological Products guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a manufacturing lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. As noted above, the DS proposed in BLA 761425, ustekinumab-xxxx, is essentially the same as the DS in BLA 761373 with respect to product quality attributes. Also, as noted above, Samsung is the applicant for both BLA 761373 and BLA 761425.

Given the above factors, a nonproprietary name for BLA 761425 that is different from that for BLA 761373 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761425 could create confusion and would not further the goals of the naming convention.

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving the same nonproprietary name for BLA 761425[e]. We based this determination upon consideration of all the factors outlined above. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name format for this BLA.

The following will be communicated to Samsung in an advice letter.

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[c] Rahbani, P.M. Proprietary Name Review for Pyzchiva (BLA 761373). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 14 Jun 2023. Nexus PNR IDs: 2023-1044725066.

[d] Patel, M. Proprietary Name Review for Pyzchiva (BLA 761425). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 26 Apr 2024. Nexus PNR IDs: 2024-1044725613.

[e] See 21 C.F.R. § 10.115(d)(3) "Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence."

Comments for Samsung for BLA 761425:

We have determined that ustekinumab-ttwe will be the proper name designated in the license should your 351(k) BLA be approved during this review cycle.

Appendix A

Proprietary Name	Stelara	Pyzchiva	Pyzchiva
Application No.	BLA 125261 BLA 761044	BLA 761373	BLA 761425
Initial Approval/ BsUFA Goal	September 25, 2009 (BLA 125261 approval) September 23, 2016 (BLA 761044 approval)	March 30, 2023 (BsUFA goal date)	January 29, 2024 (BsUFA goal date)
Active Ingredient	ustekinumab	ustekinumab-ttwe	ustekinumab-ttwe
Indication	Treatment of: *Adult patients with*: • moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). • moderately to severely active Crohn's disease (CD). • moderately to severely active ulcerative colitis. *Pediatric patients 6 years and older with*: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.	Treatment of: *Adult patients with*: • moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). • moderately to severely active Crohn's disease (CD). • moderately to severely active ulcerative colitis. *Pediatric patients 6 years and older with*: • moderate to severe plaque psoriasis, who are candidates	Treatment of: *Adult patients with*: • moderately to severely active Crohn's disease (CD). • moderately to severely active ulcerative colitis.

<table>
<tr><td></td><td>• active psoriatic arthritis (PsA).</td><td>for phototherapy or systemic therapy.
• active psoriatic arthritis (PsA).</td><td></td></tr>
<tr><td>Route of Administration</td><td>Subcutaneous Injection: 45 mg or 90 mg
Intravenous Infusion[b]: 130 mg/26 mL (5 mg/mL)</td><td>Subcutaneous Injection: 45 mg or 90 mg</td><td>Intravenous Infusion[b]: 130 mg/26 mL (5 mg/mL)</td></tr>
<tr><td>Dosage Form</td><td>Injection</td><td>Injection</td><td>Injection</td></tr>
<tr><td>Strength</td><td>45 mg/0.5 mL; 90 mg/mL; 130 mg/26 mL (5 mg/mL)</td><td>45 mg/0.5 mL; 90 mg/mL</td><td>130 mg/26 mL (5 mg/mL)</td></tr>
<tr><td>Dose and Frequency</td><td>Psoriasis Adult Subcutaneous Recommended Dosage:
<table><tr><td>Weight Range (kilograms)</td><td>Dosage Regimen</td></tr><tr><td>less than or equal to 100 kg</td><td>45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks</td></tr><tr><td>greater than 100 kg</td><td>90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks</td></tr></table>
Psoriasis Pediatric Patients (6 to 17 years old) Subcutaneous Recommended Dosage:</td><td>Psoriasis Adult Subcutaneous Recommended Dosage:
<table><tr><td>Weight Range (kilograms)</td><td>Dosage Regimen</td></tr><tr><td>less than or equal to 100 kg</td><td>45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks</td></tr><tr><td>greater than 100 kg</td><td>90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks</td></tr></table>
Psoriasis Pediatric Patients (6 to 17 years) Subcutaneous Recommended Dosage:</td><td>Crohn’s Disease and Ulcerative Colitis Initial Adult Intravenous Recommended Dosage:
A single intravenous infusion using weight-based dosing:
<table><tr><td>Weight Range (kilograms)</td><td>Recommend</td></tr><tr><td>up to 55 kg 260 mg</td><td>(2 vials)</td></tr><tr><td>greater than 55 kg to 85 kg 390 mg</td><td>(3 vials)</td></tr><tr><td>greater than 85 kg 520 mg</td><td>(4 vials)</td></tr></table></td></tr>
</table>

	Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. **Weight Range (kilograms) / Dose Regimen** less than 60 kg: 0.75 mg/kg 60 kg to 100 kg: 45 mg greater than 100 kg: 90 mg Psoriatic Arthritis Adult Subcutaneous Recommended Dosage: • The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered	Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. **Weight Range (kilograms) / Dosage Regimen** (b) (4) Psoriatic Arthritis Adult Subcutaneous Recommended Dosage: • The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered	

	subcutaneously every 12 weeks. Psoriatic Arthritis Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage: Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. Weight Range (kilograms) / Dosage Regime: less than 60 kg: 0.75 mg/kg 60 kg or more: 45 mg greater than 100 kg with co-existent moderate-to-severe plaque psoriasis: 90 mg Crohn's Disease and Ulcerative Colitis Initial Adult Intravenous Recommended Dosage: A single intravenous infusion using weight-based dosing: Weight Range (kilograms) / Recommende: up to 55 kg 260 mg: (2 vials) greater than 55 kg to 85 kg 390 mg: (3 vials) greater than 85 kg 520 mg: (4 vials)	subcutaneously every 12 weeks. Psoriatic Arthritis Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage: Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. Weight Range (kilograms) / Dosage Regi (b) (4) Crohn's Disease and Ulcerative Colitis Maintenance Adult Subcutaneous Recommended Dosage: A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.	

	Crohn's Disease and Ulcerative Colitis Maintenance Adult Subcutaneous Recommended Dosage: A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.		
How Supplied	STELARA® (ustekinumab) injection is a sterile, preservative-free, colorless to light yellow solution and may contain a few small translucent or white particles. It is supplied as individually packaged, single-dose prefilled syringes or single-dose vials. For Subcutaneous Use *Prefilled Syringes* • 45 mg/0.5 mL (NDC 57894-060-03) • 90 mg/mL (NDC 57894-061-03) Each prefilled syringe is equipped with a 27 gauge fixed ½ inch needle, a needle safety guard, and a needle cover that contains dry natural rubber. *Single-dose Vial*	Pyzchiva (ustekinumab-ttwe) injection is a clear, colorless to light yellow, sterile, preservative-free solution. It is supplied as individually packaged, single-dose prefilled syringes. For Subcutaneous Use *Prefilled Syringes* • 45 mg/0.5 mL (NDC 61314-651-01) • 90 mg/mL (NDC 61314-652-01) Each prefilled syringe is equipped with a 29 gauge fixed ½ inch needle, a needle safety guard, and a needle cover that is not made with natural rubber latex.	Pyzchiva (ustekinumab-ttwe) injection is a clear, colorless to light yellow, sterile, preservative-free solution. It is supplied as individually packaged, single-dose vials. For Intravenous Infusion Single-dose Vial • 130 mg/26 mL (5 mg/mL) (NDC 61314-654-94)

	• 45 mg/0.5 mL For Intravenous Infusion *Single-dose Vial* • 130 mg/26 mL (5 mg/mL)		
Storage	STELARA® vials and prefilled syringes must be refrigerated at 2ºC to 8ºC (36ºF to 46ºF). Store STELARA® vials upright. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. If needed, individual prefilled syringes may be stored at room temperature up to 30° C (86° F) for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature	Store Pyzchiva prefilled syringes refrigerated between 2° C to 8° C (36° F to 46° F). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. If needed, individual prefilled syringe may be stored at room temperature up to 30° C (86° F) for a maximum single period of up to 60 days in the original carton to protect from light. If not used within 60 days of room temperature storage, discard prefilled syring. The prefilled syring may be retured to the refrigerator one time only for a maximum of 3 days. If not used within 3 days, discard the prefilled syringe. Record the date when the prefilled syringe is removed	Store Pyzchiva vials refrigerated between 2° C to 8° C (36° F to 46° F). Store Pyzchiva vials upright. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Do not use Pyzchiva after the expiration date on the carton or (b) (4)

	storage. Do not use STELARA® after the expiration date on the carton or on the prefilled syringe.	from and returned to the refrigerator on the carton in the space provided. Do not use Pyzchiva after the expiration date on the carton or on the prefilled syringe.	

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
06/05/2024 08:34:25 AM

MISHALE P MISTRY
06/05/2024 04:37:14 PM

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	April 26, 2024
Application Type and Number:	BLA 761425
Product Name, Dosage Form, and Strength:	Pyzchiva (ustekinumab-ttwe)[a] injection, 130 mg/26 mL (5 mg/mL) vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Samsung Bioepis Co., Ltd (Samsung)
PNR ID #:	2024-1044725613
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature & Labeling:	Idalia E. Rychlik, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder ustekinumab-ttwe is used throughout this review to refer to the non-proprietary name and suffix for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Pyzchiva, which was found conditionally acceptable under BLA 761373 on June 14, 2023 for the 45 mg/0.5 mL and 90 mg/mL prefilled syringe and 130 mg/26 mL (5 mg/mL) vial.[b] However, since then, Samsung submitted the proposed proprietary name, Pyzchiva, under BLA 761425 for review on February 6, 2024.[c] We note that all product characteristics remain the same. However, BLA 761425 is intended to be specifically for the 130 mg/26 mL (5 mg/mL) vial used for the initial intravenous dose for Crohn's Disease (CD) and Ulcerative Colitis (UC), whereas the 45 mg/0.5 mL and 90 mg/mL prefilled syringe presentations will remain under BLA 761373.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Pyzchiva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Pyzchiva. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Pyzchiva.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Pyzchiva, 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 March 13, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Pyzchiva.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On April 24, 2024, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

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[b] Rahbani, P. Proprietary Name Review for Pyzchiva (BLA 761373). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 JUN 14. PNR ID No. 2023-1044725066.

[c] Request for Proprietary Name Review (Pyzchiva BLA 761425). Incheon (Republic of Korea): Samsung Bioepis Co., Ltd; 2024 FEB 06. Available from: \\CDSESUB1\EVSPROD\bla761425\0002\m1\us\118-prop-names\sb17_us_1-18-proprietary-names.pdf.

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, Pyzchiva, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO SAMSUNG BIOEPIS CO., LTD

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

If any of the proposed product characteristics as stated in your submission, received on February 6, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

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

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

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/

MADHURI R PATEL
04/26/2024 10:45:38 AM

YEVGENIYA M KOGAN
04/26/2024 10:52:45 AM

IDALIA E RYCHLIK
04/26/2024 11:04:07 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	1/25/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761373
Product Name and Strength:	Pyzchiva (ustekinumab-ttwe) injection Prefilled syringe: 45 mg/0.5 mL and 90 mg/mL Vial: 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Samsung Bioepis Co., Ltd. (Samsung)
FDA Received Date:	November 17, 2023
Nexus NPNS ID #:	2023-168
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Samsung for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761373.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 17, 2023, Samsung submitted an amendment to their original suffix submission dated March 30, 2023 with a list of 10 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 Samsung:

Table 1. Suffixes submitted by Samsung***

1.	(b) (4)
2.	
3.	
4.	
5.	ttwe
6.	(b) (4)
7.	
8.	
9.	
10.	

We reviewed Samsung's proposed suffixes in the order of preference listed by Samsung, along with the supporting data they submitted, using the principles described in the applicable guidance.[b]

[a] Suffix Name Request BLA 761 373. Incheon (Republic of Korea): Samsung Bioepis Co., Ltd.; 2023 Nov 17. Available from: \\CDSESUB1\EVSPROD\bla761373\0020\m1\us\118-prop-names\suffix-name-request.pdf

[b] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2.1 ustekinumab-(b) (4)

Samsung's first proposed suffix, -(b) (4), is comprised of 3 distinct letters (b) (4)

The proposed suffix -(b) (4) shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

2.2 ustekinumab-(b) (4)

Samsung's second proposed suffix, -(b) (4), is comprised of 4 distinct letters. However, we note that the suffix '(b) (4)' connotes the word (b) (4)'[a]. Therefore, we find the proposed suffix, -(b) (4), is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

2.3 ustekinumab-(b) (4)

Samsung's third proposed suffix, -(b) (4), is comprised of 3 distinct letters ((b) (4)).

The proposed suffix -(b) (4) shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

2.4 ustekinumab-(b) (4)

Samsung's fourth proposed suffix, -(b) (4), is comprised of 3 distinct letters ((b) (4)).

The proposed suffix -(b) (4) shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by

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[a] (b) (4)

the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

2.5 ustekinumab-ttwe

Samsung's fifth proposed suffix, -ttwe, is comprised of 3 distinct letters (t, w, e).

We determined that the proposed suffix -ttwe, 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 1 ANALYSIS

These findings were shared with OPDP. On December 20, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on January 25, 2024.

4 CONCLUSION

We find Samsung's proposed suffix -ttwe acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to ustekinumab-ttwe. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Samsung Bioepis Co., Ltd.

We find the nonproprietary name, ustekinumab-ttwe, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, ustekinumab-ttwe 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 will inform you of our findings.

We also note that the first 4 proposed suffixes are unacceptable for the following reasons:

1. ustekinumab-(b) (4)

The proposed suffix, -(b) (4), shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

2. ustekinumab-(b) (4)

The proposed suffix (b) (4) connotes the word '(b) (4)'[a]. Therefore, we find the proposed suffix, -(b) (4), is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

3. ustekinumab-(b) (4)

The proposed suffix -(b) (4) shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

4. ustekinumab-(b) (4)

The proposed suffix -(b) (4) shares three identical letters in identical positions with the approved suffix -(b) (4) for (b) (4). This similarity is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 75%, indicating that the suffixes are orthographically highly similar. Therefore, we find the proposed suffix -(b) (4) inconsistent with the principle outlined

[a] (b) (4)

in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix.

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
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MISHALE P MISTRY
01/26/2024 11:46:53 AM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	June 14, 2023
Application Type and Number:	BLA 761373
Product Name and Strength:	Pyzchiva (ustekinumab-xxxx) [a] injection, 45 mg/0.5 mL and 90 mg/mL prefilled syringe, 130 mg/26 mL (5 mg/mL) vial
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Samsung Bioepis Co., Ltd. (Samsung)
PNR ID #:	2023-1044725066
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Acting Division Director	Irene Z. Chan, PharmD, BCPS

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, ustekinumab -xxxx, is used throughout this review.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Pyzchiva, 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. Samsung did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

Pyzchiva (ustekinumab-xxxx) is a proposed biosimilar to US-licensed Reference Product Stelara (ustekinumab) BLA (b) (4). The following product information is provided in the proprietary name submission received on March 30, 2023.

- Intended Pronunciation: Piz-chi-va
- Active Ingredient: ustekinumab-xxxx
- Indication of Use:
  - Treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Treatment of patients 6 years or older with active psoriatic arthritis
  - Treatment of adult patients with moderately to severely active Crohn's disease
  - Treatment of adult patients with moderately to severely active ulcerative colitis
- Route of Administration: intravenous and subcutaneous
- Dosage Form: injection
- Strength: 45 mg/0.5 mL and 90 mg/mL prefilled syringe; 130 mg/26 mL (5 mg/mL) vial
- Dose and Frequency:
  - Psoriasis Recommended Adult Dosage

Weight Range (kilogram)	Dosage Regimen
less than or equal to 100 kg	45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks
greater than 100 kg	90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

In subjects weighing more than 100 kg, 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these subjects.

  - Psoriasis Pediatric Patients (6 to 17 years old) Subcutaneous Recommended Dosage

Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilogram)	Dose
60 kg to 100 kg	45 mg
greater than 100 kg	90 mg

- Psoriatic Arthritis Adult Recommended Dosage:
  - 45 mg subcutaneously initially and 4 weeks later, followed by 45 mg subcutaneously every 12 weeks.
  - For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg subcutaneously initially and 4 weeks later, followed by 90mg subcutaneously every 12 weeks.
- Psoriatic Arthritis Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage: Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilogram)	**Dosage Regimen**
60 kg to 100 kg	45 mg
greater than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg

- Crohn's Disease (CD) and Ulcerative Colitis (UC) Initial Adult Intravenous Recommended Dosage

Weight Range (kilograms)	**Recommended Dosage**
up to 55 kg	260 mg (2 vials)
greater than 55 kg to 85 kg	390 mg (3 vials)
greater than 85 kg	520 mg (4 vials)

- Crohn's Disease and Ulcerative Colitis Maintenance: 90 mg subcutaneously 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

- How Supplied: individually packaged one single-dose prefilled syringes or one single-dose vial.
- Storage:
  - Room temperature up to 30°C (86°F) for up to (b) (4) hours including infusion period. If necessary, the diluted infusion solution may be kept at 2ºC to 8ºC (36ºF to 46ºF) for up to (b) (4). After removal from refrigeration, the diluted solution may be stored at room temperature at up to 30°C (86°F) for an additional 24 hours including infusion period. Storage time at 2°C to 8°C or room temperature begins

once the diluted solution has been prepared. Do not freeze. Discard any unused portion of the infusion solution.

- Pyzchiva (ustekinumab-xxxx) is a proposed [redacted] (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Pyzchiva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Pyzchiva. The Division of Dermatology and Dentistry (DDD) declined to respond to the findings of OPDP's assessment for Pyzchiva.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Samsung indicated in their submission that the proposed name, Pyzchiva is derived from the concept that the product is manufactured by 'Samsung Bioepis' and biosimilar of 'ustekinumab (Stelara)'. This proprietary name is comprised of a single word. We note that the proposed proprietary name contains the following medical abbreviations:

- IV = Intravenous route of administration

Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of this abbreviation in the middle of the name and the lack of prominence of this abbreviation makes it unlikely that the letters 'iv' within the proposed proprietary name, Pyzchiva, could lead to confusion in this case.

- VA= Visual Acuity

Since the letter pair 'va' is included as a suffix, we considered whether the proposed name Pyzchiva could be interpreted as "Pyzchi VA", with 'VA' as a modifier or misinterpreted as 'Pyzchi visual acuity'. We note the letter pair 'VA' is not included on ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations. The letter pair 'va' is not separated from the name, capitalized, or bolded to make the letter pair more prominent in the name. Additionally, we did not identify any names that would pose a risk for confusion even if the 'va'

[b] USAN stem search conducted on April 24, 2023.

were to be separated from the remainder of the name[c]. Beyond these abbreviations, we note that Pyzchiva 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

The Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Pyzchiva at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-six (n=76) practitioners participated in DMEPA's prescription studies for Pyzchiva. One participant in the voice study misinterpreted the proposed proprietary name Pyzchiva as Izgeva which is a close phonetic variation to the marketed product Xgeva. We evaluated the name pair Pyzchiva and Xgeva further and determined the risk for confusion is adequately minimized (see appendix E).

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 16 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥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 from the FDA name 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
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	15
Low similarity name pair: combined match percentage score ≤54%	1

[c] POCA search for 'Pyzchi' conducted on May 4, 2023, in version 5.2.

[d] POCA search conducted on April 24, 2023 in version 5.2.

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

Our analysis of the 17 names contained in Table 1 determined none of the names will pose a risk for confusion with Pyzchiva as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On June 14, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Pyzchiva, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO SAMSUNG

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

If any of the proposed product characteristics as stated in your submission, received on March 30, 2023, 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. [e]

[e] 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, Cerner RxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

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

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 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[f]. 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

[f] 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 ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is 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?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Pyzchiva Study (Conducted on April 7, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Pyzchiva 390 mg via intravenous infusion over 1 hour	Pyzchiva 45 mg/0.5 mL use as directed. Dispense #1
Outpatient Prescription: Patient _____ Date 4-7-23 Address _____ ℞ Pyzchiva 45mg/0.5mL use as directed #1 MEDWATCH 1-800-FDA-1088	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Pyzchiva	

FDA Prescription Simulation Responses (<u>Aggregate Report)</u>

Study Name: Pyzchiva

258 People Received Study
76 People Responded

Study Name: Pyzchiva

Total	18	16	17	25	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
BISJIVA	0	0	1	0	1
HISDRIVA	0	0	1	0	1
HISGIBA	0	0	1	0	1
HISJABA	0	0	1	0	1
HISJIBA	0	0	1	0	1
HISJIVA	0	0	2	0	2
HIZJRUVA	0	0	1	0	1
ISCHIVA	0	0	1	0	1
ISGIVA	0	0	1	0	1
IZGEVA	0	0	1	0	1
IZJAVA	0	0	1	0	1
PISCHEVA	0	0	1	0	1
PIZGYVVA	0	0	1	0	1
PIZJIVA	0	0	1	0	1
PYRCHIVA	0	0	0	5	5
PYZCHIRA	0	0	0	1	1
PYZCHIVA	18	16	0	18	52
PYZDIVA	0	0	0	1	1
VISGAVA	0	0	1	0	1
VISJUVA	0	0	1	0	1

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

No.	**Proposed name:** Pyzchiva **Established name:** ustekinumab-xxxx **Dosage form:** injection **Strength(s):** 45 mg/0.5 mL and 90 mg/mL prefilled syringe; 130 mg/26 mL (5 mg/mL) vial **Usual Dose:** Psoriasis: weight-based dosing: 45 mg or 90 mg subcutaneously initially and 4 weeks later, followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD/UC: weight-based dosing: 260 mg or 390 mg or 520 mg intravenous once followed by 90 mg subcutaneous 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.	**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.	Pyzchiva	100	Name subject of this review.

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

No.	Name	POCA Score (%)
1.	Pexeva	56
2.	Pivya***	56
3.	Sustiva	56
4.	Parcopa	55

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

No.	**Proposed name:** Pyzchiva **Established name:** ustekinumab-xxxx **Dosage form:** injection **Strength(s):** 45 mg/0.5 mL and 90 mg/mL prefilled syringe; 130 mg/26 mL (5 mg/mL) vial **Usual Dose:** Psoriasis: weight-based dosing: 45 mg or 90 mg subcutaneously initially and 4 weeks later, followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD/UC: weight-based dosing: 260 mg or 390 mg or 520 mg intravenous once followed by 90 mg subcutaneous 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Certiva	62	This name pair has sufficient orthographic and phonetic differences.
2.	Balziva	59	This name pair has sufficient orthographic and phonetic differences.
3.	Balziva-21	59	This name pair has sufficient orthographic and phonetic differences.
4.	Balziva-28	59	This name pair has sufficient orthographic and phonetic differences.
5.	Pivlaz***	56	This name pair has sufficient orthographic and phonetic differences
6.	Spiriva	56	This name pair has sufficient orthographic and phonetic differences
7.	Xgeva	44	Orthographically, the name pair is different in length (seven vs. five letters) and the first letters (‘P’ vs. ‘X’) of this name pair and the upstroke letter ‘h’ in the 5th position of Pyzchiva, not present in Xgeva, provides sufficient orthographic differences. Phonetically, the onset of the first syllables (‘Piz’ vs. ‘X’) of this name pair sound different. Additionally, there is no overlap in strength [45 mg/0.5 mL, 90 mg/mL

No.	**Proposed name:** Pyzchiva **Established name:** ustekinumab-xxxx **Dosage form:** injection **Strength(s):** 45 mg/0.5 mL and 90 mg/mL prefilled syringe; 130 mg/26 mL (5 mg/mL) vial **Usual Dose:** Psoriasis: weight-based dosing: 45 mg or 90 mg subcutaneously initially and 4 weeks later, followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD/UC: weight-based dosing: 260 mg or 390 mg or 520 mg intravenous once followed by 90 mg subcutaneous 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.	**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**
			and, 130 mg/26 mL (5 mg/mL) vs. 120 mg/1.7 mL (70 mg/mL)], and dose (45 mg or 90 mg or 260 mg or 390 mg or 520 mg based on the indication vs. 120 mg) which may provide additional differentiation.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤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
1.	(b) (4)	58	Proposed proprietary name for NDA 214958 found unacceptable by DMEPA (OSE# 2022-1044724417). NDA 214958 approved under the proprietary name Sotyktu.
2.	(b) (4)	55	Proposed proprietary name for IND 125379 found conditionally acceptable (OSE #2018-29694627) on May 13, 2019 and withdrawn by the Applicant on June 19, 2019. NDA 212608 approved under the proprietary name Ayvakit.

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

No.	Name	POCA Score (%)
1.	Typhim Vi	57
2.	(b) (4)	56
3.	Padcev	56

[g] 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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