CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761285Orig1s000; 761331Orig1s000

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, DMAMES
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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
Center for Drug Evaluation and Research

Gerald Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Subject: Evaluation of the nonproprietary name for BLA 761331

Amgen Inc. (Amgen) submitted two Biologics License Applications (BLA 761285 and BLA 761331) pursuant to Section 351(k) of the Public Health Service Act as a biosimilar to the reference product Stelara (ustekinumab) on October 31, 2022. BLA 761285 was submitted to the Division of

Dermatology and Dentistry (DDD) for the 45 mg/0.5 mL and 90 mg/mL pre-filled syringe and 45 mg/0.5 mL single-dose vial presentations used for the subcutaneous administration of ustekinumab-xxxx for all indications. BLA 761331 was submitted to the Division of Gastroenterology for the for 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. The BsUFA goal date to take action on both applications is October 21, 2023.

The proposed product is a human interleukin -12 and -23 antagonist. Both BLAs propose the same indications (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 formulation in BLA 761331 contains the same drug substance (DS) (ustekinumab-xxxx) as BLA 761285, 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 761331 is for intravenous administration. See Appendix 1 – Product Characteristics Comparison Table for more information.

The ustekinumab-xxxx DS process used in the manufacture of the proposed vial presentation for intravenous use is the same used for the prefilled syringe and vial presentations for subcutaneous use.

Under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim[a]. If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original application. Thus, Amgen submitted two separate BLAs. However, as noted above, the DS in BLA 761285 is the same as the DS in BLA 761331, and the BLAs share the same DS formulation, dosage form, and indications, i.e., they differ only in total strength/ concentration, dose and route and frequency of 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

[a] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

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

As such, the proposed nonproprietary name suffix -auub was found conditionally acceptable[c] for BLA 761285, and if approved, the proper name designated in the license will be ustekinumab-auub. We carefully considered whether the nonproprietary name for BLA 761331 should include a different distinguishing suffix than that designated for BLA 761285 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-auub) for BLA 761331. Among the factors we have considered are the following:

1. The DS in BLA 761285 is the same as the DS in BLA 761331 and they are essentially unchanged with respect to product quality attributes (identity, purity, etc.). The main differences between the formulations are the total strength, concentration, dose, route and frequency of administration.
2. Considering that BLA 761285 and BLA 761331 share the same DS and formulation similarities, no significant differences in immunogenicity profiles is expected.
3. We note that other product characteristics are the same or similar: indications (plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis vs. Crohn's disease and ulcerative colitis), dosage form (injection), frequency of administration (initially and every 4 or 8 or 12 weeks thereafter vs. initial loading dose). See Appendix 1.
4. We note above that under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim[d]. If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original application. Thus, Amgen submitted two separate BLAs. Had one of the BLAs been approved prior to submission of the second, the additional formulation for intravenous administration for the loading dose could be managed under a supplement to the approved BLA, which would not have resulted in

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

[c] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761270. Silver Spring (MD): FDA, CDER, OSE, DMAMES (US); 2022 Apr 15. Nexus NPNS ID. 2020-80 and 2021-70.

[d] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

a change to the proper name under the approach to nonproprietary naming described in the final guidance.

5. Amgen is proposing to have the same proprietary name and U.S. prescribing information (USPI) for both BLAs. DMEPA 1 found the proposed name Wezlana conditionally acceptable on June 7, 2023.[e]
6. 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 761331, ustekinumab-xxxx, is essentially the same as the DS in BLA 761285 with respect to product quality attributes. Also, as noted above, Amgen is the applicant for BLA 761285 and BLA 761331.

Given the above factors, a different nonproprietary name for BLA 761331 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761331, 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 761331[f]. 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 Amgen in an advice letter.

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[e] Howard, C. Proprietary Name Review for Wezlana (BLA 761285 and BLA 761331). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 07 Jun 2023. Nexus PNR IDs: 2023-1044725049 and 2023-1044725050.

[f] 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 Amgen for BLA 761331:

We have determined that ustekinumab-auub will be the proper name designated in the license should your 351(a) BLA be approved during this review cycle. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review.

Appendix A

Proprietary Name	Stelara	Wezlana
Application No.	BLA 125261 BLA 761044	BLA 761286 BLA 761331
Initial Approval/ BsUFA Goal	September 25, 2009 (BLA 125261 approval) September 23, 2016 (BLA 761044 approval)	October 31, 2023 (BsUFA goal date)
Active Ingredient	ustekinumab	ustekinumab
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. • active psoriatic arthritis (PsA).	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. • active psoriatic arthritis (PsA).
Route of Administration	Subcutaneous Injection: 45 mg	Subcutaneous Injection: 45 mg Intravenous Infusion[b]: 130 mg/26 mL (5 mg/mL)

<table>
<tr><td></td><td>Intravenous Infusion[g]: 130 mg/26 mL (5 mg/mL)</td><td></td></tr>
<tr><td>Dosage Form</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; 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</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</td></tr>
</table>

[g] Note: intravenous formulation is intended only for use as *induction* therapy in CD and UC. Maintenance dose is administered using the subcutaneous formulation.

	Recommended Dosage: 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 subcutaneously every 12 weeks.	Recommended Dosage: Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. | Weight Range (kilograms)	Dosage 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 subcutaneously every 12 weeks. Psoriatic Arthritis Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage:

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 Regimen
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)	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)

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

Weight Range (kilograms)	Dosage Regimen
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)	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 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* • 45 mg/0.5 mL For Intravenous Infusion *Single-dose Vial* • 130 mg/26 mL (5 mg/mL)	TRADENAME (ustekinumab-xxxx) injection is a sterile, preservative-free, colorless to light yellow solution. 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 55513-076-01) • 90 mg/mL (NDC 55513-089-01) Each prefilled syringe is equipped with a 27 gauge fixed ½ inch needle, a needle safety guard, and a needle cover that does not contain dry natural rubber. *Single-dose Vial* • 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 storage. Do not use STELARA® after the expiration date on the carton or on the prefilled syringe.	TRADENAME vials and prefilled syringes must be refrigerated at 2° C to 8° C (36° F to 46° F). Store TRADENAME 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 syringe and 45 mg vial 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 or the 45 mg vial is first removed from the refrigerator on the carton in the space provided. Once the prefilled syringe or the 45 mg vial has been stored at room temperature, it should not be returned to the refrigerator. Discard the prefilled syringe or the 45 mg vial if not used within 30 days at room temperature storage. Do not use TRADENAME after the expiration date on the carton or on the prefilled syringe or on the 45 mg vial.

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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09/22/2023 10:20:10 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:	7/27/2023
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761285 IND 139331
Product Name and Strength:	Wezlana (ustekinumab-auub) injection, 45 mg/0.5 mL and 90 mg/mL single-dose prefilled syringe 45 mg/0.5 mL and 130 mg/25 mL single-dose vial
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Amgen Inc. (Amgen)
FDA Received Date:	October 31, 2022 (BLA) April 25, 2022 (IND)
Nexus NPNS ID #:	2022-147 (BLA) 2022-118 (IND)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Acting Director:	Irene Z Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Amgen for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761285.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On April 25, 22 (IND) and October 31, 2022 (BLA), Amgen submitted 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 Amgen:

Table 1. Suffixes submitted by Amgen***

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

[a] Request for Proprietary Name – Suffix Review BLA 761285. Thousand Oaks (CA): Amgen Inc.; 2022 Oct 31: Available from: \\CDSESUB1\EVSPROD\bla761285\0001\m1\us\proprietary-name-suffix-review.pdf

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

APPEARS THIS WAY ON ORIGINAL

[a] 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

2.1 ustekinumab-auub

Amgen's first proposed suffix, -auub, is comprised of 3 distinct letters (a, u, b). We note that the letters 'au' within the suffix represent the medical abbreviation for 'each ear'. We considered whether the inclusion of the letters 'au' within the suffix could be 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 -auub, 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 July 26, 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 July 27, 2023.

4 CONCLUSION

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

4.1 Recommendations for Amgen Inc.

We find the nonproprietary name, ustekinumab-auub, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, ustekinumab-auub 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.

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
07/27/2023 03:57:30 PM

IRENE Z CHAN
07/27/2023 06:38:35 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	June 7, 2023
Application Type and Number:	BLA 761285 and BLA 761331
Product Name and Strength:	Wezlana (ustekinumab-xxxx)[a] injection, Subcutaneous: 45 mg/0.5 mL, 90 mg/mL; Intravenous: 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Amgen Inc. (Amgen)
PNR ID #:	2023-1044725049 (BLA 761285), 2023-1044725050 (BLA 761331)
DMEPA 1 Safety Evaluator:	Corwin Howard, PharmD, RPh
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Acting Director:	Irene Z. Chan, PharmD, BCPS

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

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Amgen previously submitted the proposed proprietary name, (b) (4)*** on February 28, 2022 for review under IND 139331. However, on March 23, 2022, we found the name, (b) (4)*** unacceptable as it would misbrand the proposed product.[b]

Amgen then submitted the proposed proprietary name, (b) (4)*** for review under IND 139331 on September 26, 2022, BLA 761285 on October 31, 2022, and BLA 761331 on December 5, 2022. However, on January 26, 2023, we found the name, (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proposed proprietary name, (b) (4)***.[c]

Thus, Amgen submitted the name, Wezlana, for review on March 17, 2023 under BLA 761285 and BLA 761331.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 17, 2023.

- Intended Pronunciation: wez-LAH-nah
- Nonproprietary Name: ustekinumab-xxxx
- Indication of Use: treatment of adult patients with moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD) or moderately to severely active ulcerative colitis (UC) and pediatric patients 6 years and older with moderate to severe Ps and PsA.
- Route of Administration: subcutaneous injection, intravenous infusion.
- Dosage Form: injection
- Strength: Subcutaneous: 45 mg/0.5 mL, 90 mg/mL; Intravenous: 130 mg/26 mL (5 mg/mL)
- Dose and Frequency:

[b] Patel, M. Proprietary Name Review for (b) (4)*** (IND 139331). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US): 2022 MAR 23. PNR ID No. 2022-1044724462

[c] Howard, C. Proprietary Name Review for (b) (4)*** (IND 139331, BLA 761285, and BLA 761331). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 JAN 26. PNR ID No. 2022-1044724770 2022-1044724826 and 2022-1044724870.

- Ps and PsA (adult): 45 mg or 90 mg initially followed by additional dose 4 weeks later followed by doses every 12 weeks.
- Ps and PsA (pediatric): 45 or 90 mg, or if less than 60 kg, 0.75 mg/kg initially followed by additional dose 4 weeks later followed by doses every 12 weeks.
- CD and UC: 250 to 520 mg induction dose based on weight initially followed by 90 mg every 8 weeks.

- How Supplied: Product will be available in vials and prefilled syringes. (It is anticipated to be available in auto-injectors in the future.)
- Storage: Product should be refrigerated.
- Wezlana (ustekinumab-xxxx) is a proposed biosimilar to US-licensed Reference Product, Stelara (ustekinumab) BLA 125261 and BLA 761044.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Wezlana 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 Wezlana. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Wezlana.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Amgen did not provide a derivation or intended meaning for the proposed proprietary name, Wezlana, in their submission. This proprietary name is comprised of a single word.

We note that Wezlana contains the letter string '-la-', an abbreviation used for 'long acting' (i.e. a long acting dosage form). Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that due to the location of this abbreviation in the middle of the name and its lack of prominence, it is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we conclude that in this case, the letter string '-la-' in the name is acceptable.

[d] USAN stem search conducted on May 4, 2023.

Beyond this abbreviation, we note that Wezlana does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On March 29, 2023, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Wezlana at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-nine (n=79) practitioners participated in DMEPA's prescription studies for Wezlana. 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 search[e] identified 52 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 (b) (4) external 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%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	49
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 52 names contained in Table 1 determined none of the names will pose a risk for confusion with Wezlana as described in Appendices C through H.

[e] POCA search conducted on May 4, 2023 in version 5.2.

2.2.8 Communication of DMEPA's Determination

On June 7, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Wezlana, is conditionally acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO AMGEN INC.

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

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

[f] 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[g]. 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.

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

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation study 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.

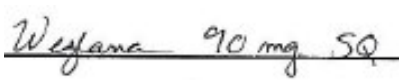
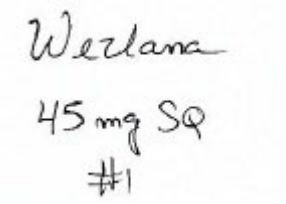
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Wezlana Study (Conducted on April 11, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: 	Wezlana Inject 45 mg SQ Dispense #1
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Wezlana	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Wezlana

257 People Received Study
79 People Responded

Total	25	19	16	19	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
LAZMANO	0	0	1	0	1
LESLANA	0	0	6	0	6
LESLANO	0	0	1	0	1
LEZLANA	0	0	1	0	1
LEZLANAH	0	0	1	0	1
WEFANA	2	0	0	0	2
WEGLANA	3	0	0	0	3
WEQLANA	1	0	0	0	1
WERLANA	0	0	0	1	1
WESFANA	11	0	0	0	11
WESFAVA	1	0	0	0	1
WESLANA	0	0	3	1	4
WEZHANA	1	0	0	0	1
WEZLANA	6	19	3	17	45

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

No.	**Proposed name:** Wezlana **Established name:** ustekinumab-xxxx **Dosage form:** injection **Strength(s):** Subcutaneous: 45 mg/0.5 mL, 90 mg/mL; Intravenous: 130 mg/26 mL (5 mg/mL) **Usual Dose:** Ps and PsA: (if less than 60 kg, 0.75 mg/kg), 45 mg or 90 mg followed by additional dose 4 weeks later followed by doses every 12 weeks. CD and UC 260 mg to 520 mg induction followed by weight- based dosing and 90 mg every 8 weeks	**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.	Wezlana***	100	Subject of this review
2.	(b) (4)***	75 (O 85)	Proposed proprietary name for IND 139331, BLA 761285, and BLA 761331 found unacceptable by DMEPA (OSE# 2022- 1044724770 (IND 139331), 2022-1044724826 (BLA 761285), and 2022-1044724870 dated January 26, 2023). Subsequently, the Applicant submitted the proposed name, Wezlana on March 17, 2023, under BLA 761285 and BLA 761331 which is the 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 **– N/A**

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

No.	**Proposed name:** Wezlana **Established name:** ustekinumab-xxxx **Dosage form:** injection **Strength(s):** Subcutaneous: 45 mg/0.5 mL, 90 mg/mL; Intravenous: 130 mg/26 mL (5 mg/mL) **Usual Dose:** Ps and PsA: (if less than 60 kg, 0.75 mg/kg), 45 mg or 90 mg followed by additional dose 4 weeks later followed by doses every 12 weeks. CD and UC 260 mg to 520 mg induction followed by weight- based dosing and 90 mg every 8 weeks	**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.	Wal-Zan	68	This name pair has sufficient orthographic and phonetic differences.
2.	Levulan	66	This name pair has sufficient orthographic and phonetic differences.
3.	Reglan	64	This name pair has sufficient orthographic and phonetic differences.
4.	Relenza	62	This name pair has sufficient orthographic and phonetic differences.
5.	Gen-Lanta	62	This name pair has sufficient orthographic and phonetic differences.
6.	Levlen	62	This name pair has sufficient orthographic and phonetic differences.
7.	Lyllana	61	This name pair has sufficient orthographic and phonetic differences.
8.	Verelan	61	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
10.	Tulana	57	This name pair has sufficient orthographic and phonetic differences.
11.	Otezla	56	This name pair has sufficient orthographic and phonetic differences.
12.	Ziana	56	This name pair has sufficient orthographic and phonetic differences
13.	Jevtana	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Elantan LA	51

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) **	63	(b) (4)
2.	Mezlin	62	Brand discontinued with no generic equivalents available. NDA 050549 withdrawn, FR effective 04/04/2005.
3.	Lazanda	61	Brand discontinued with no generic equivalents available. NDA 022569 withdrawn, FR effective 01/09/2023.
4.	Elantan	60	International product marketed in numerous international countries.
5.	(b) (4) ***	60	(b) (4)
6.	(b) (4) ***	60	(b) (4)
7.	Eqvalan	60	Veterinary product.
8.	Wolfina	58	Brand discontinued with no generic equivalents available. NDA 009255 withdrawn FR effective 03/20/1992.
9.	(b) (4) ***	58	(b) (4)

No.	Name	POCA Score (%)	Failure preventions
10.	Exolan	58	International product formerly marketed in the United Kingdom.
11.	Vivalan	58	International product formerly marketed in Belgium, Czech Republic, France, Germany, Portugal, and United Kingdom.
12.	Balanta	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Meclan	56	Brand discontinued with no generic equivalents available. NDA 050518 withdrawn FR Effective 03/20/2000.
14.	(b) (4) **	56	(b) (4)
15.	Haelan	55	International product marketed in the United Kingdom and Ireland.

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

No.	Name	POCA Score (%)
1.	Azlin	62
2.	Zevalin	62
3.	Emflaza	61
4.	Erleada	60
5.	(b) (4) ***	60
6.	Rezulin	60
7.	Xenleta	60
8.	(b) (4) ***	59
9.	(b) (4) ***	59
10.	Ashlyna	58
11.	Zolinza	58
12.	Vegzelma	57

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

No.	Name	POCA Score (%)
13.	Verluma	57
14.	Zynlonta	57
15.	(b) (4)***	56
16.	Orlenta	56
17.	Talzenna	56
18.	(b) (4)***	55
19.	Refludan	55
20.	Seizalam	55
21.	Valenac	55

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/s/

CORWIN D HOWARD
06/07/2023 06:25:51 PM

IRENE Z CHAN on behalf of MADHURI R PATEL
06/08/2023 05:01:45 PM
Signed on behalf of Madhuri Patel

IRENE Z CHAN
06/08/2023 05:04:23 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	January 26, 2023
Application Type and Number:	IND 139331, BLA 761285 and BLA 761331
Product Name and Strength:	(b) (4) (ustekinumab-xxxx)[a] injection, Subcutaneous: 45 mg/0.5 mL, 90 mg/mL; Intravenous: 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Amgen Inc. (Amgen)
PNR ID #:	2022- 1044724770 (IND 139331), 2022-1044724826 (BLA 761285), and 2022-1044724870 (BLA 761331)
DMEPA 1 Safety Evaluator:	Corwin D. Howard, PharmD, RPh
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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

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CORWIN D HOWARD
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MISHALE P MISTRY on behalf of MADHURI R PATEL
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