CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761338Orig1s000
761338Orig2s000

PROPRIETARY NAME REVIEW(S)

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)

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Date of This Review:	12/11/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761338
Product Name and Strength:	Steqeyma (ustekinumab-stba) 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)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
Nexus NPNS ID #:	2024-274
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Deputy Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -stba, for BLA 761338, which was found conditionally acceptable on April 4, 2024[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761338.

1.1 Regulatory History

Celltrion submitted a four-letter suffix, -stba, for BLA 761338 on June 30, 2023[b]. However, BLA 761338 received a Complete Response (CR) letter on September 30, 2024[c]. Thus, Celltrion submitted a Class 2 Resubmission on October 16, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -stba, using the principles described in the applicable guidance[d].

We determined that the proposed suffix -stba, 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 11, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on December 11, 2024.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for Steqeyma ustekinumab-stba (BLA 761338). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2024 Apr 04. Nexus No.: 2023-182.

[b] Non-Proprietary Name BLA 761338. Incheon (Republic of Korea): Celltrion, Inc.; 2023 Jun 30. Available from: \\CDSESUB1\EVSPROD\bla761338\0001\m1\us\nonproprietary-name.pdf

[c] Oussova, T. Complete Response (BLA 761338). Silver Spring (MD): FDA, CDER, OND, DDD (US); 2024 Sep 30.

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

4 CONCLUSION

We find the suffix -stba acceptable and recommend the nonproprietary name ustekinumab-stba be used throughout the draft labels and labeling.

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
12/11/2024 03:59:01 PM

MISHALE P MISTRY
12/13/2024 02:34:53 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:	December 3, 2024
Application Type and Number:	BLA 761338
Product Name, Dosage Form, and Strength:	Steqeyma (ustekinumab-stba) 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:	Celltrion, Inc. (Celltrion)
PNR ID #:	2024-1044726048
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Celltrion previously submitted the proposed proprietary name, Steqeyma, under IND 146085 on April 6, 2023 and BLA 761338 on July 3, 2023, and we found the name conditionally acceptable on September 27, 2023.[a] However, BLA 761338 received a Complete Response (CR) letter on September 30, 2024 due to issues with product quality.[b]

Thus, Celltrion submitted the proposed proprietary name, Steqeyma, for review on October 16, 2024 under BLA 761338.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 16, 2024[c] and the prescribing information received on October 16, 2024[d].

Table 1. Relevant Product Information for Steqeyma	
Intended pronunciation:	Ste-QEY-ma
Nonproprietary name:	ustekinumab-stba
Indication:	- Plaque Psoriasis (PsO) treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. - Psoriatic Arthritis (PsA) treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis. - Crohn's Disease (CD) treatment of adult patients with moderately to severely active Crohn's disease. - Ulcerative Colitis (UC)

[a] Rahbani, P. Proprietary Name Review for Steqeyma (IND 146085 and BLA 761338). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 SEP 27. PNR ID No. 2023-1044725085 (IND) and 2023-1044725220 (BLA).

[b] Rhee, S on behalf of Oussova, T. Complete Response for BLA 761338. Silver Spring (MD): FDA, CDER, OND, Division of Dermatology and Dentistry (DDD) (US); 2024 SEP 30.

[c] Request for Proprietary Name Review (Steqeyma BLA 761338). Incheon (ROK): Celltrion, Inc.; 2024 OCT 16. Available from: \\CDSESUB1\EVSPROD\bla761338\0033\m1\us\proprietary-names.pdf.

[d] Proposed prescribing information for Steqeyma. Incheon (ROK): Celltrion, Inc.; 2024 OCT 16. Available from: \\CDSESUB1\EVSPROD\bla761338\0033\m1\us\draft-labeling-text-track.docx.

Table 1. Relevant Product Information for Steqeyma	
	treatment of adult patients with moderately to severely active ulcerative colitis.
Dosage Form:	injection
Strength:	45 mg/0.5 mL and 90 mg/mL prefilled syringe, 130 mg/26 mL (5 mg/mL) vial
Route of administration:	subcutaneous intravenous

Table 1. Relevant Product Information for Steqeyma	
Dose and frequency:	Psoriasis Adult Subcutaneous Recommended Dosage: - less than or equal to 100kg: 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks - greater than 100kg: 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks 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. - 60 kg to 100kg: 45 mg - greater than 100kg: 90 mg There is no dosage form for STEQEYMA that allows weight-based dosing for pediatric patients below 60 kg. 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 100kg, 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. - 60kg or more: 45mg - greater than 100kg with co-existent moderate-to severe plaque psoriasis: 90 mg There is no dosage form for STEQEYMA that allows weight-based dosing for pediatric patients below 60 kg. Crohn's Disease and Ulcerative Colitis Initial Adult Intravenous Recommended Dosage: A single intravenous infusion using weight-based dosing: - up to 55kg: 260 mg (2 vials) - greater than 55kg to 85kg: 390 mg (3 vials) - greater than 85kg: 520 mg (4 vials)

Table 1. Relevant Product Information for Steqeyma	
	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:	For Subcutaneous Use *Prefilled Syringes* • 45 mg/0.5 mL (NDC 72606-027-01) • 90 mg/mL (NDC 72606-028-01) Each prefilled syringe is equipped with a 27-gauge fixed ½ inch needle, a needle safety guard, and a needle cover. For Intravenous Infusion *Single-dose Vial* • 130 mg/26 mL (5 mg/mL) (NDC 72606-029-01)
Storage:	Store vials and prefilled syringes refrigerated between 2°C to 8°C (36°F to 46°F). Store 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 vials and prefilled syringes may be stored at room temperature up to 30°C (86°F) for a maximum single period of up to 15 days in the original carton to protect from light. Record the date when the vial or the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Once a vial or a syringe has been stored at room temperature, do not return to the refrigerator. Discard the vial or syringe if not used within 15 days at room temperature storage. Do not use after the expiration date on the carton or on the vial or the prefilled syringe
Reference Product:	Steqeyma (ustekinumab-stba) is a proposed biosimilar to US-licensed Reference Product, Stelara (ustekinumab) BLA 125261 and BLA 761044

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Steqeyma 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 Steqeyma. The Division of

Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Steqeyma.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

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

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-nine (n=89) practitioners participated in DMEPA's prescription simulation studies for Steqeyma. 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[f] identified 28 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We also evaluated previously identified names taking into account the change in the room temperature storage of the prefilled syringes (for a maximum single period of up to 15 days instead of (b) (4) days). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Steqeyma. Therefore, we identified three names not previously analyzed. These names are included in Table 2 below.

[e] USAN stem search conducted on November 25, 2024.

[f] POCA search conducted on November 25, 2024 in version 5.9.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
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 three names contained in Table 2 determined none of the names will pose a risk for confusion with Steqeyma as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On December 3, 2024, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Steqeyma, is conditionally acceptable.

3.1 COMMENTS TO CELLTRION, INC.

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

If any of the proposed product characteristics as stated in your submission, received on October 16, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

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

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs@FDA Glossary of Terms, available at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[g]

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[h]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

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

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

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

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

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

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		

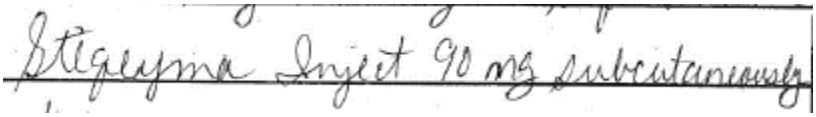
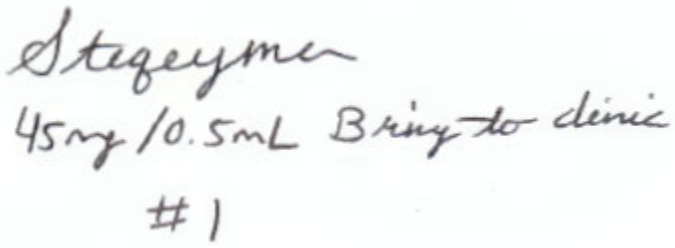
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses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

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

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤54%).**
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Steqeyma Study (Conducted on 11/1/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Steqeyma 45 mg per 0.5 mL. Bring to clinic. Dispense 1.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Steqeyma	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Steqeyma People Received Study: 185 People Responded: 89					
Total	27	24	16	22	89
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
DAKAMA	0	0	1	0	1
STACAMA	0	0	2	0	2
STAKAYMA	0	0	2	0	2
STAKEMA	0	0	1	0	1
STEBCAYMA	0	0	1	0	1
STECAMA	0	0	2	0	2

STEGEYMA	1	3	0	0	4
STEGEYMER	0	1	0	0	1
STEKAMA	0	0	2	0	2
STEKAYMA	0	0	3	0	3
STEQEYMA	4	9	0	22	35
STEQEYME	0	2	0	0	2
STEQEYMER	0	4	0	0	4
STEQEYMI	0	1	0	0	1
STEQEYMIN	0	1	0	0	1
STEQEYMU	0	1	0	0	1
STEQLYMA	1	0	0	0	1
STIGBYMA	1	0	0	0	1
STIGEYMA	3	0	0	0	3
STIGEYMA INJECTION	1	0	0	0	1
STIGLYMA	1	0	0	0	1
STIQBYMA	1	0	0	0	1
STIQEYMA	10	2	0	0	12
STIQUEYMA	1	0	0	0	1
STIQUYMA	2	0	0	0	2
STIQUYNA	1	0	0	0	1
STKAIMA	0	0	1	0	1
STUBCAIMA	0	0	1	0	1

APPEARS THIS WAY ON ORIGINAL

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

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)	58

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: Steqeyma Pronunciation: Ste-QEY-ma Established name: ustekinumab-stba Dosage form: injection Strength(s): 45 mg/0.5 mL and 90 mg/mL prefilled syringe, 130 mg/26 mL (5 mg/mL) vial Dosage: Ps and PsA: 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD and UC: 260 mg or 390 mg or 520 mg intravenously once followed by 90 mg subcutaneously 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.	Starjemza***	58	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.	(b) (4)	54

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

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

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

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
12/03/2024 04:22:34 PM

YEVGENIYA M KOGAN
12/03/2024 04:55:38 PM

IDALIA E RYCHLIK
12/10/2024 12:12:03 PM

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:	4/4/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761338
Product Name and Strength:	Steqeyma (ustekinumab-stba) 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)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
FDA Received Date:	June 30, 2023
Nexus NPNS ID #:	2023-182
DMEPA 2 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 Celltrion for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761338.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 30, 2023, Celltrion submitted a list of 8 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Celltrion also provided findings from their evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Celltrion:

Table 1. Suffixes submitted by Celltrion***

1.	stba
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	

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

[a] Non-Proprietary Name BLA 761338. Incheon (Republic of Korea): Celltrion, Inc.; 2023 Jun 30. Available from: \\CDSESUB1\EVSPROD\bla761338\0001\m1\us\nonproprietary-name.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-stba

Celltrion's first proposed suffix, -stba, is comprised of four distinct letters.

We determined that the proposed suffix -stba, 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 April 3, 2024, 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 April 4, 2024.

4 CONCLUSION

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

4.1 Recommendations for Celltrion, Inc.

We find the nonproprietary name, ustekinumab-stba, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, ustekinumab-stba 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
04/04/2024 04:12:10 PM

MISHALE P MISTRY
04/04/2024 04:27:10 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:	September 27, 2023
Application Type and Number:	IND 146085 BLA 761338
Product Name and Strength:	Steqeyma (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:	Celltrion Inc.
PNR ID #:	2023-1044725085 (IND) 2023-1044725220 (BLA)
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

[a] The non-proprietary name 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 for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Steqeyma, 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. Celltrion Inc. did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

Steqeyma (ustekinumab-xxxx) is a proposed biosimilar to US-licensed Stelara (ustekinumab) (). The following product information is provided in the proprietary name submission received on April 6, 2023 under IND 146085, and July 3, 2023 under BLA 761338.

- Intended Pronunciation: Ste-QEY-ma
- Active Ingredient: ustekinumab-xxxx
- Indication of Use:

  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 (UC)

  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: intravenous infusion or subcutaneous injection
- 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 (Ps)**

    Adult

    For patients weighing 100 kg or less, the recommended dose is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks

    For patients weighing more than 100 kg, the recommended dose is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

    Pediatric

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

- **Psoriatic Arthritis (PsA)**

  Adult

  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.

  Pediatric

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

- **Crohn's Disease (CD) and Ulcerative Colitis (UC)**

  Adult (Initial): A single intravenous infusion using weight-based dosing

  Adult (Maintenance): A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter

- How Supplied: individually packaged one single-dose prefilled syringe or one single-dose vial.

- Storage: Vials and pre-filled syringes must be refrigerated at 2°C to 8ºC (36°F to 46ºF). Do not freeze. Do not shake. Store in the original carton until time of use to protect from light. 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 (b) (4) days in the original carton to protect from light.
- Steqeyma (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, Steqeyma.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Steqeyma 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 Steqeyma. The Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Steqeyma.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On July 19, 2023, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Steqeyma at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-eight (n= 88) practitioners participated in DMEPA's prescription studies for Steqeyma. The responses did not overlap with any currently marketed products nor did the responses sound

[b] USAN stem search conducted on July 10, 2023.

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[c] identified 26 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. 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%	24
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 26 names contained in Table 1 determined none of the names will pose a risk for confusion with Steqeyma as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On September 27, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Steqeyma, 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 CELLTRION INC.

[c] POCA search conducted on July 10, 2023 in version 5.2.

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

If any of the proposed product characteristics as stated in your submission, received on July 3, 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. [d]

[d] 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[e]. 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.

[e] 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 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 **<u>with</u>** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

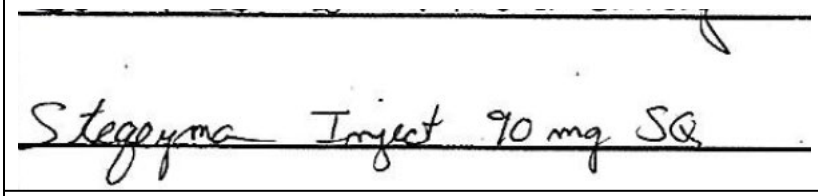
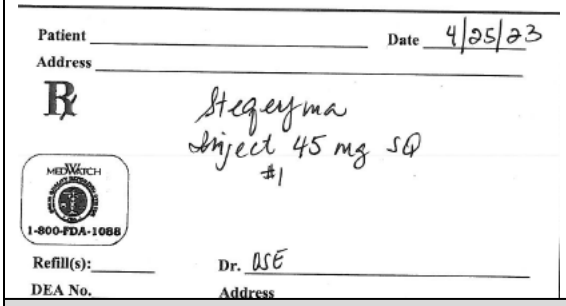
Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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.

<u>Appendix B:</u> Prescription Simulation Samples and Results

<u>Figure 1. Steqeyma Study (Conducted on April 25, 2023)</u>

Handwritten Medication Order/Prescription	**Verbal Prescription**

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

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Steqeyma - 2023-04-25
People Received Study: 256
People Responded: 88

Total	21	25	19	23	88
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
STAKIMA	0	0	2	0	2
STECKEMA	0	0	2	0	2
STECKIMA	0	0	2	0	2
STEGEYMA	2	2	0	0	4
STEGOYMA	1	0	0	0	1
STEKCHEMA	0	0	1	0	1
STEKEEMA	0	0	3	0	3
STEKEMA	0	0	1	0	1

STEKIMA	0	0	7	0	7
STEPKEEMA	0	0	1	0	1
STEQERJINA	0	1	0	0	1
STEQERJMA	0	2	0	0	2
STEQERYMA	0	2	0	0	2
STEQEYMA	15	17	0	23	55
STEQUYMA	2	0	0	0	2
STEQYMA INJECT	1	0	0	0	1
STEZERYMA	0	1	0	0	1

** U.S. FDA - RX Study*
** RX Study Version 4.1 (2023-06-28)*

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

No.	**Proposed name:** Steqeyma **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:** Ps and PsA: 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD and UC: 260 mg or 390 mg or 520 mg intravenously once followed by 90 mg subcutaneously 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.	Steqeyma	100	This name 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

No.	Name	POCA Score (%)
1.	(b) (4)	58

No.	Name	POCA Score (%)
2.	Staxyn	57
3.	(b) (4)	56

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:** Steqeyma **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:** 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 45 mg or 90 mg subcutaneously every 12 weeks. CD and UC: 260 mg or 390 mg or 520 mg intravenously once followed by 90 mg subcutaneously 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.	Stimate	61	This name pair has sufficient orthographic and phonetic differences.
2.	Stay Clean	58	This name pair has sufficient orthographic and phonetic differences.
3.	Strattera	58	This name pair has sufficient orthographic and phonetic differences.
4.	Systane	58	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4)	57	This name pair has sufficient orthographic and phonetic differences.
6.	Stendra	56	This name pair has sufficient orthographic and phonetic differences.
7.	Ustekinumab	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.	Amnesteem	50

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.	Sterane	60	Brand discontinued with no generic equivalents available. NDA 011446 (injection) withdrawn FR effective 06/11/1998. NDA 009996 (tablets) withdrawn FR effective 09/17/2001.
2.	(b) (4)	59	(b) (4)
3.	Styrene	58	Product is not a drug. Styreneis a synthetic chemical used in the manufacturing of plastics, rubber, and resins
4.	Styramate	57	Established name in combination with paracetamol for Sinaxamol, an international product formerly marketed in South Africa.
5.	Sebacate	56	Product is not a drug. Sebacate is a salt of sebacic acid.
6.	(b) (4)	56	(b) (4)
7.	Stannate	55	Product is not a drug. Stannate is a salt of stannic acid.

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

No.	Name	POCA Score (%)
1.	Pet-Ema	60
2.	Aspartame	58
3.	Fleet Enema	58
4.	Cetaderm	56
5.	Estraderm	56

[f] 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 (%)
6.	Treximа	56
7.	Vitastem	56

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/s/

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