CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761406Orig1s000
761406Orig2s000

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)

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

Date of This Review:	8/1/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761406
Product Name and Strength:	Yesintek (ustekinumab-kfce) injection, Pre-filled syringe: 45 mg/0.5 mL and 90 mg/mL Vial: 45 mg/0.5 mL and 130 mg/26 mL (20 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Biocon Biologics, Inc. (Biocon)
Nexus NPNS ID #:	2023-218
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 suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761406.

1.1 Regulatory History

Biocon was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

ustekinumab-kfce

FDA generated a four-letter suffix, -kfce. This suffix was evaluated using the principles described in the applicable guidance[b].

We determined that the FDA-generated suffix -kfce, 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 17, 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 August 1, 2024.

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[a] Mistry, M. Nonproprietary Name General Advice Letter for BLA 761406. Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US) 2024 Jan 08.

[b] 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 -kfce acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to ustekinumab-kfce. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Biocon Biologics, Inc.

We find the nonproprietary name, ustekinumab-kfce, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, ustekinumab-kfce 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 this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
08/01/2024 09:01:24 AM

MISHALE P MISTRY
08/06/2024 03:28:02 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:	February 23, 2024
Application Type and Number:	BLA 761406
Product Name, Dosage Form, and Strength:	Yesintek (ustekinumab-xxxx)[a] injection, 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2023-1044725489
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	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.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Yesintek, 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. Biocon submitted an external name study, conducted by [redacted][b], for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 29, 2023[c].

Table 1. Relevant Product Information for Yesintek	
Intended pronunciation:	yeh sin tek
Nonproprietary name:	ustekinumab-xxxx
Indication:	**Psoriasis (Ps)** treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy **Psoriatic Arthritis (PsA)** treatment of patients 6 years or older with active psoriatic arthritis. **Crohn's Disease (CD)** treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** treatment of adult patients with moderately to severely active ulcerative colitis.
Dosage Form:	injection
Strength:	45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL)
Route of administration:	subcutaneous injection and intravenous infusion

[b] Proprietary Name Safety Summary for Yesintek. [redacted] 2023 NOV 15. Available from: \\CDSESUB1\EVSPROD\bla761406\0001\m1\us\118-proprietary-names\annexure-2-proprietary-name-assessment-report-yesintek.pdf.

[c] Proposed Prescribing Information (BLA 761406). Cambridge (MA): Biocon Biologics Inc.; 2023 NOV 29. Available from: \\CDSESUB1\EVSPROD\bla761406\0001\m1\us\114-labeling\draft\labeling\draft-labeling-text-tracked-changes-word.docx.

Table 1. Relevant Product Information for Yesintek	
Usual dosage and frequency:	**Psoriasis Recommended Adult Subcutaneous Dosage:** • For patients weighing 100 kg or less, the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients weighing more than 100 kg, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. In subjects weighing more than 100 kg, 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these subjects **Psoriasis Pediatric Patients (6 to 17 years old) Subcutaneous Recommended Dosage:** Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. • less than 60 kg: 0.75 mg/kg • 60 kg to 100 kg: 45 mg • more than 100 kg: 90 mg **Psoriatic Arthritis Recommended Adult Subcutaneous Dosage:** • The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg 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. • 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 Recommended Initial Adult Intravenous Dosage:**

Table 1. Relevant Product Information for Yesintek	
	A single intravenous infusion using weight-based dosing: • 55 kg or less: 260 mg (2 vials) • more than 55 kg to 85 kg: 390 mg (3 vials) • more than 85 kg: 520 mg (4 vials) **Crohn's Disease and Ulcerative Colitis Recommended Maintenance Adult Subcutaneous Dosage:** A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter
How Supplied:	a sterile, preservative-free, colorless to pale yellow solution. It is supplied as individually packaged, single-dose prefilled syringes or single-dose vials. <u>For Subcutaneous Use</u> Prefilled Syringes • 45 mg/0.5 mL (NDC- 83257-023-41) • 90 mg/mL (NDC- 83257-025-41) Each prefilled syringe is equipped with a 29 gauge fixed ½ inch needle, a needle safety guard, and a needle cover (b) (4) (b) (4). Single-dose Vial • 45 mg/0.5 mL (NDC- 83257-024-11) <u>For Intravenous Infusion</u> Single-dose Vial • 130 mg/26 mL (5 mg/mL) (NDC- 83257-026-11)

Table 1. Relevant Product Information for Yesintek	
Storage:	vials and prefilled syringes must be refrigerated at 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 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 after the expiration date on the carton or on the prefilled syringe.
Reference Product:	Yesintek (ustekinumab-xxxx) is a proposed interchangeable 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, Yesintek.

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

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

[d] USAN stem search conducted on February 2, 2024.

the letter strings 'es', a medical abbreviation for extra strength, and 'in', a medical abbreviation for intranasal. We typically discourage the inclusion of medical abbreviations in proprietary names; however, given the location of the letter strings, 'es' and 'in', embedded in the middle of the name and its lack of prominence, it is unlikely to be separated from the surrounding letters that could lead to confusion. Beyond these abbreviations, we note that Yesintek does not contain any other 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 January 3, 2024, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Yesintek at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Eighty-four (n=84) practitioners participated in DMEPA's prescription studies for Yesintek. 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 99 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 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 2. 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%	90
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 99 names contained in Table 2 determined none of the names will pose a risk for confusion with Yesintek as described in Appendices C through H.

[e] POCA search conducted on February 2, 2024 in version 5.5.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 22, 2024, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Yesintek, 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 BIOCON BIOLOGICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 29, 2023, 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.[f]

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

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

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

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

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

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

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

the confusion of drug names[9]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

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

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

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

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

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

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

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

concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

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

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).			
Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

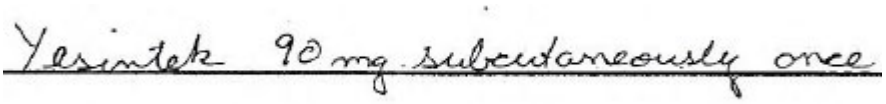
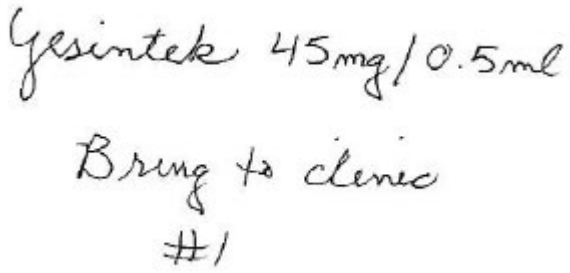
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.
For single strength products, also consider circumstances where the strength may not be expressed.
For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.
To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:
• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.
• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
• *FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

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

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

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Yesintek Study (Conducted on 1/30/2024)

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

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Yesintek People Received Study: 165 People Responded: 84					
Total	18	25	16	25	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
YASINTEK	0	0	1	0	1
YASYNTIQ	0	0	1	0	1
YERIMTEK	1	0	0	0	1
YERSINTEK	1	0	0	0	1
YESENTECK	0	0	1	0	1
YESENTEK	0	0	1	0	1
YESIMTEK	0	1	0	0	1
YESINTEC	0	0	2	0	2
YESINTECH	0	0	2	0	2
YESINTECK	0	1	0	0	1
YESINTEK	16	22	4	25	67

YESINTEK 45 MG/0.5 ML	0	1	0	0	1
YESINTEQ	0	0	2	0	2
YESSINTEC	0	0	1	0	1
YESYNTEK	0	0	1	0	1

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

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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.	Yesintek***	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 – 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: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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.	Isentress	68	Orthographically, the first letters ('Y' vs. 'I'), infixes ('sin' vs. 'ntr'), and suffixes ('tek' vs. 'ess') provide sufficient orthographic differences. Phonetically, the first syllables ('yeh' vs. 'i') and ending sounds of the last syllables ('ek' vs. 'ess') sound different. The following differences in product characteristics may help to mitigate the risk of name confusion: There is no overlap in dosage forms (injection vs. tablet, chewable tablet, for oral suspension) and strengths [45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) vs. 25 mg, 100 mg, and 400 mg,] and because Isentress is available in multiple dosage forms and strengths, either the dosage form or strength would need to be specified for Isentress on a prescription/medication order.

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			Additionally, there is no overlap in route of administration (subcutaneous or intravenous vs. oral) if included on a prescription/ medication order. When all the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
2.	Phenytek	68	This name pair has sufficient orthographic and phonetic differences.
3.	Sprintec	66	This name pair has sufficient orthographic and phonetic differences.
4.	Syntest	66	Root name for Syntest DS and Syntest HS. Syntest HS is deactivated and no generic equivalents are available. Orthographically when comparing the root names, the prefixes (‘Ye’ vs. ‘Sy’), infixes (‘sin’ vs. ‘nte’), and suffixes (‘tek’

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			vs. 'st') provide sufficient orthographic differences. Phonetically, when comparing the root names, the Yesintek name contains an extra syllable. The first syllables ('yeh' vs. 'syn') and the second syllables ('sin' vs. 'test') sound different. The following differences in product characteristics may help to mitigate the risk of name confusion: There is no overlap in dosage form (injection vs. tablet), route of administration (subcutaneous or intravenous vs. oral), and frequency of administration (subcutaneously initially, 4 weeks later and then every 12 weeks or intravenous infusion once then subcutaneously every 8 weeks vs. once daily) if included on a prescription/ medication order.

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			When all the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
5.	Lucentis	63	Orthographically, the first letters (‘Y’ vs. ‘L’) and the last letters (‘k’ vs. ‘s’) provide some orthographic differences. Phonetically, the first syllables (‘yeh’ vs. ‘lu) and the ending sounds of the last syllables (‘ek’ vs. ‘is’) sound different. The following differences in product characteristics may help to mitigate the risk of name confusion: There is no overlap in route of administration (subcutaneous vs. intravitreal) if included on a prescription/ medication order. When all the aforementioned mitigations are considered in totality, we find the risk

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			of confusion is adequately minimized in this case.
6.	Centex	62	Root name for Centex PSE. Orthographically, the lengths of the root names differ by 2 letters. Additionally, when comparing the root names, the first letters ('Y' vs. 'C') of the name pair, and the letter string, '-si-', and upstroke letter 'k' in the 8th position of Yesintek, not present in Centex, provide sufficient orthographic differences. Phonetically, when comparing the root names, the Yesintek name contains an extra syllable. The first syllables ('Yeh' vs. 'cen') and 2nd syllables ('sin' vs. 'tex') sound different. The following differences in product characteristics may help to mitigate the risk of name confusion:

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			There is no overlap in dosage form (injection vs. extended-release tablet), route of administration (subcutaneous or intravenous vs. oral), and frequency of administration (subcutaneously initially, 4 weeks later and then every 12 weeks or intravenous infusion once then subcutaneously every 8 weeks vs. twice daily) if included on a prescription/ medication order. Additionally, there is no overlap in strengths [45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) vs. 600-1200 mg] if included on a prescription/ medication order. When all the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
7.	Pytest Kit	62	This name pair has sufficient orthographic and phonetic differences.
8.	Lotensin	61	This name pair has sufficient orthographic and phonetic differences.
9.	Elitek	60	This name pair has sufficient orthographic and phonetic differences.
10.	Sinemet	60	This name pair has sufficient orthographic and phonetic differences.
11.	Aygestin	58	This name pair has sufficient orthographic and phonetic differences.
12.	Desitin	58	This name pair has sufficient orthographic and phonetic differences.
13.	Tri-Sprintec	58	This name pair has sufficient orthographic and phonetic differences.
14.	Visine Ac	58	This name pair has sufficient orthographic and phonetic differences.
15.	Digitek	57	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
16.	Kesimpta	56	This name pair has sufficient orthographic and phonetic differences.
17.	Sinex	56	This name pair has sufficient orthographic and phonetic differences.
18.	Entex	55	Root name for Entex LQ. Orthographically, the lengths of the root names differ by 3 letters. Additionally, when comparing the root names, the letter strings ('Yesin' vs. 'En') provide sufficient orthographic differences. Phonetically, when comparing the root names, the Yesintek name contains an extra syllable. The first syllables ('Yeh' vs. 'en') and 2nd syllables ('sin' vs. 'tex') sound different. The following differences in product characteristics may help to mitigate the risk of name confusion: There is no overlap in dosage form (injection vs. liquid), route of

No.	Proposed name: Yesintek Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) Usual dose: Ps and PsA: 0.75 mg/kg (if weighing less than 60 kg), 45 mg or 90 mg subcutaneously initially and 4 weeks later followed by 0.75 mg/kg (if weighing less than 60 kg), 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
			administration (subcutaneous or intravenous vs. oral), and frequency of administration (subcutaneously initially, 4 weeks later and then every 12 weeks or intravenous infusion once then subcutaneously every 8 weeks vs. every 4 hours) if included on a prescription/ medication order. Additionally, there is no overlap in strengths [45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL (5 mg/mL) vs. 100 mg-10 mg/5 mL]. When all the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

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

No.	Name	POCA Score (%)
1.	Eye-Sine	54
2.	Cytisine	52
3.	Cytosine	51
4.	Estinyl	50
5.	(b) (4)***	50
6.	(b) (4)***	49
7.	Lysine	48
8.	Tyrosine	44

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)***	70	Proposed proprietary name for IND 110489 found unacceptable by DMEPA (PNR ID No. 2022-1044724459 dated 06/23/2022) due to conflict with the pending name Defencath***. Subsequently, the proposed proprietary name Lymphir*** was found conditionally acceptable for BLA 761312 (PNR ID No. 2022-1044724914 dated 03/23/2023). The Applicant indicated that their preferred name is Lymphir***. BLA 761312 was issued a Complete Response on July 28, 2023.
2.	Wytensin	70	Brand discontinued with no generic equivalents available. NDA 018587 withdrawn FR effective 06/04/2004
3.	Diatensec	62	International product formerly marketed in the United Kingdom.
4.	Sinodec	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Atensine	60	International product formerly marketed in the United Kingdom and Ireland.
6.	Mytussin Pe	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Trintex	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	(b) (4)***	60	Proposed proprietary name for NDA 208743 found unacceptable by DMEPA (OSE # 2016-8278936 dated

No.	Name	POCA Score (%)	Failure preventions
			August 22, 2016). NDA 208743 approved under the proprietary name Tymlos.
9.	(b) (4) ***	59	Proposed proprietary name (b) (4) (b) (4) (b) (4) however, the entire application (b) (4) was withdrawn by the Applicant (b) (4) (b) (4)
10.	(b) (4) ***	58	Proposed (b) (4) for the proprietary name Paragard (b) (4) *** for IND 156353. The proposed proprietary name, (b) (4) *** was found unacceptable by DMEPA due to misbranding concern (OSE# 2022-1044724675 dated 01/13/2023). Subsequently, the proposed proprietary name (b) (4) *** for NDA 018680/S-074 was found unacceptable by DMEPA due to misbranding concern (OSE # 2023-1044725023 dated 04/17/2023). IND 156353 is active, NDA 018680/S-074 is pending and no new names have been submitted.
11.	Levsinex	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Myoscint	58	Brand discontinued with no generic equivalents available. BLA 103634.
13.	Skintx	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Yeast-X Int	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Bentex	56	International product formerly marketed in the United Kingdom.
16.	Cystine	56	Product is not a drug. It is the oxidized derivative of the amino acid cysteine.
17.	Entex S	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found conditionally acceptable by DMEPA (OSE (b) (4) (b) (4)). IND (b) (4) was inactivated per sponsor request (b) (4).
19.	Mintex	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
20.	Mytussin Dac	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
21.	Rautensin	56	Brand discontinued with no generic equivalents available. NDA 009215 withdrawn FR effective 03/20/1992.
22.	T-Tussin Pe	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
23.	Tussin Pe	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
24.	Tussinate	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
25.	Centussin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Cysteine	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
27.	Sinufed	55	Name identified in RxNorm database. Root name for Sinufed Pediatric and Sinufed Timecelles, which are deactivated and no generic equivalents are available.
28.	Sinuvent	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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.	Senatec	64
2.	Gentak	62
3.	(b) (4) ***	61
4.	Sensipak	60
5.	Synotic	60
6.	Phenytex	59
7.	Asendin	58
8.	Cystex	58

[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 (%)
9.	Definity	58
10.	Desenex	58
11.	Renitec	58
12.	Tecentriq	58
13.	Cenestin	57
14.	Easotic	57
15.	Mekinist	57
16.	Strensiq	57
17.	Triesence	57
18.	Cestex	56
19.	Cosentyx	56
20.	(b) (4) ***	56
21.	Definity Rt	56
22.	Diphentann	56
23.	Elinest	56
24.	Infestat	56
25.	Inositech	56
26.	Isentress Hd	56
27.	Isodettes	56
28.	Minitec	56
29.	Rinatec	56
30.	Senokot	56
31.	Sil Tex	56
32.	Tencet	56
33.	Unitensen	56
34.	Zincate	56
35.	Bosentan	55
36.	Desonate	55
37.	Evitex	55
38.	(b) (4) ***	55
39.	K-Vescent	55
40.	Mesantoin	55

No.	Name	POCA Score (%)
41.	Movantik	55
42.	Neocin Pg	55
43.	Nystex	55
44.	Symdeko	55

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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02/23/2024 08:52:16 AM

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