CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761326Orig2s000

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:	February 24, 2026
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761326
Product Name and Strength:	Awiqli FlexTouch (insulin icodec-abae) injection 700 units/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Novo Nordisk Inc. (Novo Nordisk)
FDA Received Date:	September 26, 2025
Nexus NPNS ID #:	2025-353
DMEPA 2 Biologics Suffix Specialist:	Carlos Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 Purpose of Review

This review is to reassess our evaluation of the four-letter suffix –abae for BLA 761326, which was found conditionally acceptable on May 16, 2024,[a] for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761326.

2 Regulatory History

The proposed suffix -abae was found conditionally acceptable for BLA 761326 on May 16, 2024.[a] However, BLA 761326 received a Complete Response (CR) letter on July 10, 2024.[b] Thus, Novo Nordisk submitted a Class 2 Resubmission on September 26, 2025.

3 Assessment of the Nonproprietary Name

We reassessed the previously conditionally acceptable suffix -abae, using the principles described in the Nonproprietary Naming of Biological Products guidance.[c]

We determined that the proposed suffix -abae, is not too similar to any other product's 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 lead be misinterpreted, and does not make misrepresentations with respect to safety and efficacy of the product.

4 Communication of DMEPA 1 Analysis

These findings were shared with OPDP. On January 21, 2026, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on February 24, 2026.

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[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for insulin icodec-abae (BLA 761326). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 May 16. Nexus ID.: 2023-198.
[b] Yanoff, L.B. Complete Response (BLA 761326). Silver Spring (MD): FDA, CDER, OND, Office of Cardiology, Hematology, Endocrinology, and Nephrology (US); 2024 Jul 07
[c] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

5 Conclusion

We find the suffix –abae acceptable and recommend the nonproprietary name insulin icodec-abae be used throughout the draft labels and labeling. DMEPA 1 will communicate our findings to the Applicant via letter.

5.1 Recommendations for Novo Nordisk Inc.

We find the nonproprietary name, insulin icodec-abae, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, insulin icodec-abae 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. 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
02/24/2026 02:11:26 PM

MISHALE P MISTRY
02/24/2026 02:17:55 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)

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Date of This Review:	November 18, 2025
Application Type and Number:	BLA 761326
Product Name, Dosage Form, and Strength:	Awiqli FlexTouch (insulin icodec-xxxx)[a] injection, 700 units/mL
Total Product Strength:	Trade packs: 2,100 units/3 mL pre-filled, multi-dose pen 1,050 units/1.5 mL pre-filled, multi-dose pen Sample packs: 1,050 units/1.5 mL pre-filled, multi-dose pen 700 units/mL pre-filled, multi-dose pen
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novo Nordisk, Inc. (Novo Nordisk)
PNR ID #:	2025-1044726742
DMEPA 1 Safety Evaluator:	Susan Shermock, PharmD, CPPS
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder insulin icodec-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, Awiqli FlexTouch, 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. Novo Nordisk submitted an external name study, conducted by (b) (4)[b] for this proposed proprietary name. The submitted external name study was previously reviewed under IND 137406 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Novo previously submitted the proposed proprietary name, Awiqli, under IND 137406 on September 7, 2021, and under BLA 761326 on April 10, 2023. In their submissions, they also submitted a name study to support the use of the modifier "FlexTouch" for this product; therefore, we reviewed the proposed proprietary names Awiqli and Awiqli FlexTouch in our previous reviews. On March 2, 2022 and June 29, 2023 we found the names, Awiqli and Awiqli FlexTouch, conditionally acceptable.[c,d]

However, BLA 761326 received a Complete Response on July 10, 2024 for product quality and clinical issues. At the time of the complete response action, the FDA administratively split the BLA 761326 as follows:

- BLA 761326/Original 1 – Type 1 diabetes mellitus in adults
- BLA 761326/Original 2 – Type 2 diabetes mellitus in adults

On September 26, 2025, Novo Nordisk resubmitted BLA 761326/original 2 for the indication of Type 2 diabetes. The resubmission included a request for proprietary name review for the proposed proprietary name, Awiqli FlexTouch.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 26, 2025.[e]

Table 1. Relevant Product Information for Awiqli FlexTouch	
Intended Pronunciation:	Ah-wik-lee
Nonproprietary name:	insulin icodec-xxxx

(b) (4)

[c] Conrad A. Proprietary Name Review for Awiqli FlexTouch (IND 137406). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 2. PNR ID No. 2021-1044724171.

[d] Conrad A. Proprietary Name Review for Awiqli FlexTouch (BLA 761326). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 JUN 29. PNR ID No. 2023-1044725092.

[e] Request for Proprietary Name Review (BLA 761326 Awiqli). Plainsboro (NJ): Novo Nordisk, Inc.; 2025 SEP 26. Available from: \\CDSESUB1\EVSPROD\bla761326\0080\m1\us\m1-18-request-prop-name-rev.pdf.

Table 1. Relevant Product Information for Awiqli FlexTouch	
Indication:	To improve glycemic control in patients with diabetes mellitus
Dosage Form:	Injection
Strength:	700 units/mL
Route of Administration:	Subcutaneous
Dose and Frequency:	Dose based on individual titration administered once weekly: • For insulin naïve type 2 diabetes (T2D) patients: starting dose of 70 units • For basal switch T2D patients (b) (4) [redacted]
How Supplied:	Trade packs: 2,100 units/3 mL pre-filled, multi-dose pen 1,050 units/1.5 mL pre-filled, multi-dose pen Sample packs: 1,050 units/1.5 mL pre-filled, multi-dose pen 700 units/mL pre-filled, multi-dose pen
Storage:	Refrigerate at 36°F to 46°F (2°C to 8°C)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Awiqli FlexTouch 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 Awiqli FlexTouch. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Awiqli FlexTouch.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[f] USAN stem search conducted on October 16, 2025.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

The proposed proprietary name is comprised of the root name Awiqli and the device modifier FlexTouch. Novo indicated in their submission that the proposed proprietary name, Awiqli, is "not derived from any particular concept". However, we acknowledge that the pronunciation of the proposed name approximates "a weekly", which appears to reference the once weekly dosing interval proposed for this product.

The appropriateness of the modifier, FlexTouch, was previously evaluated and we maintain our agreement with our previous determination.[g]

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Awiqli FlexTouch at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Seventy-six practitioners participated in FDA's prescription simulation studies for Awiqli FlexTouch.

One respondent in the Computerized Prescription Order Entry (CPOE) study commented that the proposed name, Awiqli, *"Sounds like you do it weekly A WIQ LI (A WEEKLYLY) DRUG."* We note this concern was evaluated in previous reviews and we maintain that this comment does not change our overall determination on the acceptability of this name.[g,h] Two respondents in the outpatient written study misinterpreted the proposed proprietary name as "Avigli Flextouch", which is close to Aviglic. We note that Aviglic is an international product marketed in India. We placed Aviglic in Appendix G.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[i] identified nine names with a combined phonetic and orthographic 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 note that none of the product characteristics have changed, and we agree with the findings from our previous review for the names evaluated previously.

We identified one name not previously analyzed. This name is included in Table 2 below.

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[g] Conrad, A. Proprietary Name Review for Awiqli FlexTouch (IND 137406). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 2. PNR ID No. 2021-1044724171.

[h] Conrad, A. Proprietary Name Review for Awiqli FlexTouch (BLA 761326). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Jun 29. PNR ID No. 2023-1044725092.

[i] POCA search conducted on October 16, 2025 in version 5.15.0.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search and FDA Prescription Simulation Study. 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%	0

2.2.7 SAFETY ANALYSIS OF NAMES IDENTIFIED

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

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On November 18, 2025, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Awiqli FlexTouch, is conditionally acceptable.

3.1 COMMENTS TO NOVO NORDISK, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 26, 2025, are altered prior to approval of the 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.[j]

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.

[j] 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 (Tables 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 that 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[k]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

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

[k] 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

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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

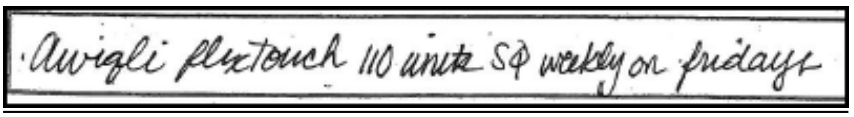
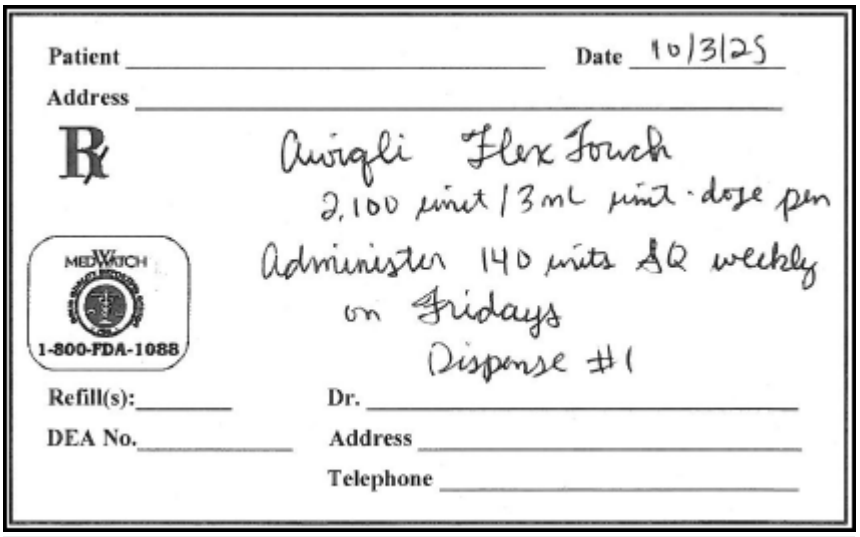
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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 as 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 names 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. Awiqli FlexTouch Study (Conducted on 10/3/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Inpatient:  Outpatient:  	Awiqli FlexTouch 2,100 unit/3 mL multi-dose pen Administer 140 units SQ Weekly on Fridays Dispense #1
Computerized Prescription Order Entry (CPOE) Study Sample (displayed as sans-serif, 12-point, bold font)	
Awiqli FlexTouch	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Awiqli FlexTouch People Received Study: 154 People Responded: 76					
Total	19	19	19	19	76
INTERPRETATION	INPATIENT WRITTEN	OUTPATIENT WRITTEN	VERBAL	CPOE	TOTAL
AIOQLI FLEXTOUCH	0	1	0	0	1
AIVIQLI FLEX TOUCH	0	2	0	0	2
ARVIQLI FLEXTOUCH	0	1	0	0	1
AVIGLI FLEXTOUCH	1	0	0	0	1
AVIQLI	0	1	0	0	1
AWEEKLY FLEX TOUCH	0	0	1	0	1

AWEEKLY FLEXTOUCH	0	0	2	0	2
AWICKLI FLEXTOUCH	0	0	1	0	1
AWICKLY FLEX TOUCH	0	0	2	0	2
AWICKLY FLEXTOUCH	0	0	1	0	1
AWICKLY LUXTOUCH	0	0	1	0	1
AWIGLI FLEX TOUCH	0	1	0	0	1
AWIGLI FLEXTOUCH	6	1	0	0	7
AWIKLI FLEXTOUCH	0	0	1	0	1
AWIKLY FLEX TOUCH	0	0	2	0	2
AWIKLY FLEXTOUCH	0	0	4	0	4
AWIQLI	0	1	0	0	1
AWIQLI FLEX TOUCH	1	7	0	0	8
AWIQLI FLEXTOUCH	10	4	0	19	33
AWIQLI PLEXTOUCH	1	0	0	0	1
AWIQLY FLEXTOUCH	0	0	1	0	1
OWIKLY FLEX TOUCH	0	0	1	0	1
OWIKLY LUXTOUCH	0	0	1	0	1
WICKLI FLEXTOUCH	0	0	1	0	1

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 – 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: Awiqli FlexTouch Pronunciation: Ah-wik-lee Established name: insulin icodec-xxxx Dosage form: injection Strength(s): 700 units/mL Dosage: Dose based on individual titration administered once weekly	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.	Iqlik	62	This name pair has sufficient orthographic and phonetic differences. This is a modifier for the root name Lequembi.

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	Aviglic	64	See FMEA in Section 2.2.4.

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/

SUSAN B SHERMOCK
11/18/2025 10:25:10 AM

DAMON A BIRKEMEIER
11/18/2025 10:58:10 AM

IDALIA E RYCHLIK
11/18/2025 11:03:41 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	5/16/2024
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761326
Product Name and Strength:	Awiqli FlexTouch (insulin icodec-abae) injection 700 units/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Novo Nordisk Inc. (Novo Nordisk)
FDA Received Date:	April 10, 2023
Nexus NPNS ID #:	2023-198
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 Novo Nordisk for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761326.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On April 10, 2023, Novo Nordisk submitted a list of 4 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Novo Nordisk 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 Novo Nordisk:

Table 1. Suffixes submitted by Novo Nordisk***

1.	(b) (4)
2.	
3.	abae
4.	(b) (4)

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

(b) (4)

[a] Request for Suffix Review BLA 761326. Plainsboro (NJ): Novo Nordisk Inc.; 2023 Apr 2023. Available from: \\CDSESUB1\EVSPROD\bla761326\0001\m1\us\m1-12-4-request-for-suffix-review.pdf

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

(b) (4)

2.3 insulin icodec-abae

Novo Nordisk's third proposed suffix, -abae, is comprised of 3 distinct letters (a, b, e).

We determined that the proposed suffix -abae, 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 May 2, 2024, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. We acknowledge OPDP's comment that the suffix -abae may evoke the colloquial term 'bae'. However, DMEPA 1 does not consider this

to be a safety concern. DMEPA 1 also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on May 16, 2024.

4 CONCLUSION

We find Novo Nordisk's proposed suffix -abae acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to insulin icodec-abae. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Novo Nordisk Inc.

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

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

(b) (4)

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

/s/

CARLOS M MENA-GRILLASCA
05/16/2024 11:40:10 AM

MISHALE P MISTRY
05/16/2024 02:42:52 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	June 29, 2023
Application Type and Number:	BLA 761326
Product Name and Strength:	Awiqli FlexTouch (insulin icodec) injection, 700 units/mL
Total Product Strength:	700 units/mL prefilled pen 1,050 units per 1.5 mL prefilled pen 2,100 units per 3 mL prefilled pen
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novo Nordisk Inc. (Novo)
PNR ID #:	2023-1044725092
DMEPA 1 Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDCES
DMEPA 1 Team Leader:	Idalia E. Rychlik, PharmD
DMEPA 1 Director (Acting):	Irene Z. Chan, Pharm.D., BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Awiqli FlexTouch, 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. Novo submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 137406 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Novo previously submitted the proposed proprietary name, Awiqli***, under IND 137406 on September 7, 2021. In their submission, they also submitted a name study to support the use of the modifier "FlexTouch" for this product; therefore, we reviewed Awiqli*** and Awiqli FlexTouch*** in our review. On March 2, 2022, we found the names, Awiqli*** and Awiqli FlexTouch***, acceptable.[a]

Thus, Novo submitted the name, Awiqli FlexTouch, for review on April 10, 2023 under BLA 761326.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name and labeling submissions received on April 10, 2023.

- Intended Pronunciation: [Ah-wik-lee]
- Nonproprietary Name: insulin icodec
- Indication of Use: long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 700 units/mL
- Dose and Frequency: individualized dose administered once weekly

  (b) (4)

  - *Type 2 Diabetes Mellitus:* The recommended starting dose in insulin naïve patients with type 2 diabetes mellitus is 70 units administered once weekly.
- How Supplied: 1 mL, 1.5 mL, and 3 mL prefilled disposable PDS290 pen-injector (FlexTouch device platform)

[a] Conrad, A. Proprietary Name Review for Awiqli FlexTouch (IND 137406). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 2. PNR ID No. 2021-1044724171.

- Storage: refrigerate at 36°F−46°F(2°C−8°C)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Awiqli FlexTouch would not misbrand the proposed product on April 26, 2023. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Awiqli FlexTouch. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Awiqli FlexTouch.

2.2 SAFETY ASSESSMENT

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

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

The proposed proprietary name is comprised of the root name Awiqli and the device modifier FlexTouch. Novo indicated in their submission that the proposed proprietary name, Awiqli, is "not derived from any particular concept". However, we acknowledge that the pronunciation of the proposed name approximates "a weekly", which appears to reference the once weekly dosing interval proposed for this product.

The appropriateness of the modifier, FlexTouch, was previously evaluated and we agree with our previous determination.[c]

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 24, 2023, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) reiterated their prior concerns with the proposed name because the pronunciation approximates "a weekly". This concern was previously evaluated and documented in our prior review.[c] Of note, the DDLO later determined that they had no concerns and would align with DMEPA's decision regarding the name. Thus, on June 22, 2023, they did not forward any additional comments or concerns relating to the proposed name, Awiqli.

[b] USAN stem search conducted on April 27, 2023.

[c] Conrad, A. Proprietary Name Review for Awiqli FlexTouch (IND 137406). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 2. PNR ID No. 2021-1044724171.

2.2.4 FDA Name Simulation Studies

Eighty-eight (88) practitioners participated in DMEPA's prescription studies for Awiqli FlexTouch. 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[d] identified eight names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated these names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we did not identify any names that were not previously identified.

2.2.6 Communication of DMEPA's Determination

On June 29, 2023, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Awiqli FlexTouch, is conditionally acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO NOVO NORDISK INC.

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

In your request for proprietary review for Awiqli, you indicated that the proposed name is "not derived from any particular concept". However, our review determined that the pronunciation of the proposed name (Ah-wik-lee) sounds similar to "a weekly", which appears to reference the once weekly dosing interval currently proposed for this product. Please note that if any of the proposed product characteristics as stated in your April 10, 2023 submission, including frequency of administration, are altered prior to approval of the marketing application, the acceptability of the proposed name will need to be reevaluated.

[d] POCA search conducted on April 27, 2023 in version 5.2.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

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

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

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

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

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

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

[f] 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 **with** overlapping or similar strengths or doses.

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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Awiqli FlexTouch Study (Conducted on April 25, 2023)

<table>
<tr><th>Handwritten Medication Order/Prescription</th><th>Verbal Prescription</th></tr>
<tr><td>Medication Order:
Awiqli FlexTouch Inject (b) (4) units SQ x 1 dose today

Outpatient Prescription:
Awiqli FlexTouch
Inject (b) (4) units SQ every week
on Mondays
#1 pen</td><td rowspan="3">Awiqli FlexTouch inject (b) (4) units SubQ every week on Mondays

Dispense # 1 pen</td></tr>
<tr><td>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</td></tr>
<tr><td>Awiqli FlexTouch</td></tr>
</table>

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Awiqli FlexTouch
As of Date 5/25/2023

256 People Received Study
88 People Responded

Study Name: Awiqli FlexTouch

Total	21	23	19	25	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
AHWEEKLY FLEX TOUCH	0	0	1	0	1
AHWEEKLY FLEXTOUCH	0	0	1	0	1
AHWICKLY FLEXTOUCH	0	0	2	0	2
AUWEEKLY FLEXTOUCH	0	0	1	0	1
AWEEKLY FLEX TOUCH	0	0	1	0	1
AWEEKLY FLEXTOUCH	0	0	1	0	1
AWICKLI FLEX TOUCH	0	0	1	0	1
AWICKLY FLEXTOUCH	0	0	6	0	6
AWICLY FLEX TOUCH	0	0	1	0	1
AWIGLI FLEX TOUCH	1	0	0	2	3
AWIGLI FLEXTOUCH	3	0	0	4	7
AWIGLI FLEXTOUGH	1	0	0	0	1
AWIGLI FLEXTTOUCH	1	0	0	0	1
AWIKLY FLEX TOUCH	0	0	3	0	3
AWIKLY FLEXTOUCH	0	0	1	0	1
AWIQLI	1	0	0	1	2
AWIQLI FLEX TOUCH	2	0	0	9	11
AWIQLI FLEXTOUCH	11	23	0	8	42
AWIQLI FLEXTOUCH INJECT	1	0	0	0	1
AWIZLI FLEX TOUCH	0	0	0	1	1

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 – 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 – N/A

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

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

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

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

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/s/

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