

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761325Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	1/10/2025
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761325
Product Name and Strength:	Merilog (insulin aspart-szjj) injection, 100 units/mL Merilog Solostar (insulin aspart-szjj) injection 100 units/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	sanofi-aventis U.S. LLC (sanofi)
Nexus NPNS ID #:	2024-277
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -szjj, for BLA 761325, which was found conditionally acceptable on May 4, 2023^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761325.

1.1 Regulatory History

FDA generated a four-letter suffix, -szjj, for BLA 761325 on May 4, 2023^a. However, BLA 761325 received a Complete Response (CR) letter on September 8, 2023^b. Thus, sanofi submitted a Class 2 Resubmission on August 16, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously generated four-letter suffix, -szjj, using the principles described in the applicable guidance^c.

We determined that the FDA-generated suffix -szjj, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On December 18, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on January 10, 2025.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for insulin aspart-szjj (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 May 04. Nexus No.: 2022-132.

^b Archdeacon, P. Complete Response (BLA 761325). Silver Spring (MD): FDA, CDER, OND, DDLO (US); 2023 Sep 08.

^c 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 -szjj acceptable and recommend the nonproprietary name insulin aspart-szjj be used throughout the draft labels and labeling.

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

/s/

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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:	October 22, 2024
Application Type and Number:	BLA 761325
Product Name, Dosage Form, and Strength:	Merilog (insulin aspart-szjj) injection, 100 units/mL Merilog SoloStar (insulin aspart-szjj) injection, 100 units/mL
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sanofi-Aventis (Sanofi)
PNR ID #:	2024-1044725950 and 2024-1044725954
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Merilog, 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. Sanofi submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761325 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Sanofi previously submitted the proposed proprietary names (b) (4) ** and (b) (4) SoloStar*** on May 11, 2018, under IND (b) (4). We found the proposed names acceptable on November 07, 2018.^b

Sanofi previously submitted the proposed proprietary names (b) (4) *** and (b) (4) SoloStar*** under BLA 761325 on September 15, 2022. However, on April 13, 2023, we found the names, (b) (4) *** and (b) (4) SoloStar*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4).

Sanofi previously submitted the proposed proprietary names Merilog and Merilog SoloStar under BLA 761325 on June 01, 2023, and we found the names conditionally acceptable on August 16, 2023.^d However, BLA 761325 received a complete response due to product quality issues on September 08, 2023.^e

Thus, Sanofi resubmitted the proposed proprietary names Merilog and Merilog SoloStar for review with their class 2 resubmission on August 16, 2024, under BLA 761325.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 16, 2024.^f

Table 1. Relevant Product Information for Merilog
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^a REQUEST FOR PROPRIETARY NAME REVIEW Proprietary Name Assessment. (b) (4) 2023 May 29. Available from: <\\CDSESUB1\EVSPROD\bla761325\0049\m1\us\proprietary-name.pdf>.

^b Mistry, M. Proprietary Name Review Memorandum for (b) (4) SoloStar (IND 133678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Nov 7. PNR ID No. 2018-23010611 and 2018-23072015.

^c Mistry, M. Proprietary Name Review for (b) (4) (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 APR 13. PNR ID No. 2022-1044724757.

^d Vee, S. Proprietary Name Review for Merilog (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Aug 16. PNR ID No. 2023-1044725162 and 2023-1044725166.

^e Oyewole, M. General correspondence complete response for BLA 761325, insulin aspart-szjj. Silver Spring (MD): FDA, CDER, OND (US); 2023 Sep 08.

^f Request for Proprietary Name Review Merilog and Merilog SoloStar BLA 761325. Bridgewater (NJ): Sanofi-Aventis; 2024 Aug 16. Available from: <\\CDSESUB1\EVSPROD\bla761325\0049\m1\us\proprietary-name.pdf>.

Table 1. Relevant Product Information for Merilog	
Intended pronunciation:	Mer-ih-lawg Mer-ih-lawg soh-loh-stahr
Nonproprietary name:	insulin aspart-szjj
Indication:	to improve glycemic control in adults and children with diabetes mellitus
Dosage Form:	injection
Strength:	100 units/mL
Route of administration:	subcutaneous injection, (b) (4) (b) (4)
Dose and frequency:	Individualized dosage based on (b) (4) the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal. • Subcutaneous injection: Inject within 5-10 minutes before a meal (b) (4)
How Supplied:	10 mL multiple-dose vial and 3 mL single-patient-use SoloStar prefilled pen
Storage:	Refrigerate between 2°C and 8°C (36°F to 46°F). Do not freeze and do not expose to excessive heat or light.
Reference Product:	Merilog (insulin aspart-szjj) is a proposed biosimilar to US-licensed Reference Product, Novolog (insulin aspart) BLA 020986.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Merilog 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 Merilog. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not comment on the findings of OPDP's assessment for Merilog.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.⁹

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Sanofi did not provide a derivation or intended meaning for the proposed proprietary name, Merilog, in their submission. This proprietary name is comprised of a single word that contains the letter string “-er-”, which is a medical abbreviation for “extended release”. We determined that the location of the letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, we do not object to the inclusion of the letter string “-er-” in the infix of the proposed proprietary name.

Beyond these abbreviations, we note that Merilog does not contain any additional components (i.e., route of administration, dosage form, etc.) that can contribute to medication error. We further evaluate the use of the modifier, SoloStar, in Section 2.2.8 below.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On September 5, 2024, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Merilog at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-six (n = 86) and Eighty-four (n = 84) practitioners participated in DMEPA’s prescription simulation studies for Merilog and Merilog SoloStar, respectively.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name “Mebhydroline” from the static pick list even though the correct name, Merilog SoloStar, was also contained on the list. The CPOE simulation software generated a static pick list that included “Mebhydroline” as the first name on the list while “Merilog SoloStar” was listed fourteenth. We note the respondent took longer to select a name from the static list compared to the amount of time taken to select remaining study names that were included in the CPOE study (21 seconds for Merilog SoloStar *versus* 10-12 seconds for each other name). We also note for the other study names, the correct proposed names were either first or second in the static pick list compared to the fourteenth for Merilog SoloStar.

This name pair has sufficient phonetic and orthographic differences, as supported by a combined Phonetic and Orthographic Computer Analysis (POCA) score of 44%, suggesting low similarity between the names Merilog and Mebhydroline. Additionally, Mebhydroline is an international drug product marketed in Ukraine and Russia. We note that the proprietary name,

⁹ USAN stem search conducted on August 28, 2024.

Mebhydroline, is not marketed in the United States. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized. We evaluate the name Mebhydroline in Appendix G.

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

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^h identified 110 names with a combined score of $\geq 55\%$ or an individual orthographic or phonetic score of $\geq 70\%$. 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. Therefore, we identified four names not previously analyzed. These names are included in Table 2 below.

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 $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	4
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

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

2.2.8 SAFETY ANALYSIS OF THE PROPOSED MODIFIER, “SOLOSTAR”

The proposed proprietary name, Merilog SoloStar, is comprised of the root name Merilog and the device modifier SoloStar. We note that the SoloStar modifier denotes the specific type of pen injector used for the product that will be packaged as a prefilled pen. This is consistent with the Sanofi brand of approved SoloStar disposable pens (i.e., Admelog SoloStar, Lantus SoloStar,

^h POCA search conducted on September 9, 2024 in version 5.9.

Toujeo SoloStar and Apidra SoloStar). Of note, the device modifier SoloStar was previously reviewed, and we maintain our conclusion that the use of this modifier is appropriate.ⁱ

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On October 22, 2024, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Merilog, is conditionally acceptable.

3.1 COMMENTS TO SANOFI-AVENTIS

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

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

ⁱ Mistry, M. Proprietary Name Review Memorandum for (b) (4) SoloStar (IND 133678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Nov 7. PNR ID No. 2018-23010611 and 2018-23072015.

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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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.
 - o 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.

- o 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-

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

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
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	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	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 $\leq 54\%$).

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. Merilog Study (Conducted on 9/6/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Merilog 4 units SQ before each meal</i> <u>Outpatient Prescription:</u> Patient _____ Date _____ Address _____ R  <i>Merilog</i> <i>Injection 5 units subcut</i> <i>before each meal</i> <i>#1</i> Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	Merilog Inject 5 units subcutaneously before each meal. Dispense #1.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Merilog	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Merilog					
People Received Study: 190					
People Responded: 86					
Total	20	23	21	22	86
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MARALOG	0	0	5	0	5

MARCLOG	0	0	1	0	1
MARILOG	0	0	4	0	4
MERALOG	0	0	2	0	2
MERILOG	20	22	1	22	65
MERILOG INJECTION	0	1	0	0	1
MIRALOG	0	0	7	0	7
MURALOG	0	0	1	0	1

Figure 2. Merilog SoloStar Study (Conducted on 9/13/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Merilog SoloStar 5 units subQ</i>	Merilog Inject 5 units subcutaneously 5 to 10 minutes before a meal. Dispense #3.
<u>Outpatient Prescription:</u> Patient _____ Date _____ Address _____ R <i>Merilog Solo Star</i> <i>Inject 5 units subQ 5-10 minutes before a meal</i> <i>#3</i>  MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Merilog SoloStar	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Merilog SoloStar					
People Received Study: 187					
People Responded: 84					
Total	22	25	16	21	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MEBHYDROLINE	0	0	0	1	1
MERALOG FILISTAR	0	0	1	0	1
MERALOG SOLOSTAR	0	0	1	0	1
MERILOG	1	1	0	0	2
MERILOG SOLASTAR	1	0	0	0	1
MERILOG SOLO STAR	0	18	0	0	18
MERILOG SOLO START	0	2	0	0	2
MERILOG SOLO STR	0	1	0	0	1
MERILOG SOLOSTAR	8	3	0	20	31
MERILOG SOLSTAR	1	0	0	0	1
MERILOG SOLUSTAR	7	0	0	0	7
MERILOG SOLUSTART	1	0	0	0	1
MEROLOG SOLOSTAR	0	0	1	0	1
MERULOG SOLOSTAR	1	0	0	0	1
MERVILOG SOLOSTAR	1	0	0	0	1
MIRALOG SOLOSTAR	0	0	1	0	1
MOROLOG SOLOSTAR	0	0	1	0	1
MURALOG SOLASTAR	0	0	1	0	1
MURALOG SOLOSTAR	0	0	7	0	7
MURALOR SOOASTAR	0	0	1	0	1
MURILOG SOLISTAR	0	0	1	0	1
MUROLOG SOLOSTAR	0	0	1	0	1
MVULOG SOLOSTAR	1	0	0	0	1

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

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Merilog Pronunciation: Mer-ih-lawg Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Dosage: Individualized dose administered 5 to 10 minutes before a meal	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.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.
2.	Kenalog-40	56	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is $\leq 54\%$) – 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.	Mebhydroline	44	International product marketed in Ukraine and Russia.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion¹

No.	Name	POCA Score (%)
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¹ 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 (%)
1.	(b) (4) ***	59
2.	Proloid	56

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/s/

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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:	October 25, 2024
Application Type and Number:	BLA 761325
Product Name, Dosage Form, and Strength:	Merilog (insulin aspart-szjj) injection, 100 units/mL Merilog SoloStar (insulin aspart-szjj) injection, 100 units/mL
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sanofi-Aventis (Sanofi)
PNR ID #:	2024-1044725950 and 2024-1044725954
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Merilog, 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. Sanofi submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761325 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Sanofi previously submitted the proposed proprietary names (b) (4) ** and (b) (4) SoloStar*** on May 11, 2018, under IND (b) (4). We found the proposed names acceptable on November 07, 2018.^b

Sanofi previously submitted the proposed proprietary names (b) (4) ** and (b) (4) SoloStar*** under BLA 761325 on September 15, 2022. However, on April 13, 2023, we found the names, (b) (4)*** and (b) (4) SoloStar*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4).

Sanofi previously submitted the proposed proprietary names Merilog and Merilog SoloStar under BLA 761325 on June 01, 2023, and we found the names conditionally acceptable on August 16, 2023.^d However, BLA 761325 received a complete response due to product quality issues on September 08, 2023.^e

Thus, Sanofi resubmitted the proposed proprietary names Merilog and Merilog SoloStar for review with their class 2 resubmission on August 16, 2024, under BLA 761325.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 16, 2024.^f

Table 1. Relevant Product Information for Merilog
--

^a REQUEST FOR PROPRIETARY NAME REVIEW Proprietary Name Assessment. (b) (4) 2023 May 29. Available from: <\\CDSESUB1\EVSPROD\bla761325\0049\m1\us\proprietary-name.pdf>.

^b Mistry, M. Proprietary Name Review Memorandum for (b) (4) SoloStar (IND 133678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Nov 7. PNR ID No. 2018-23010611 and 2018-23072015.

^c Mistry, M. Proprietary Name Review for (b) (4) (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 APR 13. PNR ID No. 2022-1044724757.

^d Vee, S. Proprietary Name Review for Merilog (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Aug 16. PNR ID No. 2023-1044725162 and 2023-1044725166.

^e Oyewole, M. General correspondence complete response for BLA 761325, insulin aspart-szjj. Silver Spring (MD): FDA, CDER, OND (US); 2023 Sep 08.

^f Request for Proprietary Name Review Merilog and Merilog SoloStar BLA 761325. Bridgewater (NJ): Sanofi-Aventis; 2024 Aug 16. Available from: <\\CDSESUB1\EVSPROD\bla761325\0049\m1\us\proprietary-name.pdf>.

Table 1. Relevant Product Information for Merilog	
Intended pronunciation:	Mer-ih-lawg Mer-ih-lawg soh-loh-stahr
Nonproprietary name:	insulin aspart-szjj
Indication:	to improve glycemic control in adults and children with diabetes mellitus
Dosage Form:	injection
Strength:	100 units/mL
Route of administration:	subcutaneous injection, (b) (4) (b) (4)
Dose and frequency:	Individualized dosage based on (b) (4) the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal. • Subcutaneous injection: Inject within 5-10 minutes before a meal (b) (4)
How Supplied:	10 mL multiple-dose vial and 3 mL single-patient-use SoloStar prefilled pen
Storage:	Refrigerate between 2°C and 8°C (36°F to 46°F). Do not freeze and do not expose to excessive heat or light.
Reference Product:	Merilog (insulin aspart-szjj) is a proposed biosimilar to US-licensed Reference Product, Novolog (insulin aspart) BLA 020986.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Merilog 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 Merilog. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not comment on the findings of OPDP's assessment for Merilog.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.⁹

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Sanofi did not provide a derivation or intended meaning for the proposed proprietary name, Merilog, in their submission. This proprietary name is comprised of a single word that contains the letter string “-er-”, which is a medical abbreviation for “extended release”. We determined that the location of the letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, we do not object to the inclusion of the letter string “-er-” in the infix of the proposed proprietary name.

Beyond these abbreviations, we note that Merilog does not contain any additional components (i.e., route of administration, dosage form, etc.) that can contribute to medication error. We further evaluate the use of the modifier, SoloStar, in Section 2.2.8 below.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On September 5, 2024, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Merilog at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-six (n = 86) and Eighty-four (n = 84) practitioners participated in DMEPA’s prescription simulation studies for Merilog and Merilog SoloStar, respectively.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name “Mebhydroline” from the static pick list even though the correct name, Merilog SoloStar, was also contained on the list. The CPOE simulation software generated a static pick list that included “Mebhydroline” as the first name on the list while “Merilog SoloStar” was listed fourteenth. We note the respondent took longer to select a name from the static list compared to the amount of time taken to select remaining study names that were included in the CPOE study (21 seconds for Merilog SoloStar *versus* 10-12 seconds for each other name). We also note for the other study names, the correct proposed names were either first or second in the static pick list compared to the fourteenth for Merilog SoloStar.

This name pair has sufficient phonetic and orthographic differences, as supported by a combined Phonetic and Orthographic Computer Analysis (POCA) score of 44%, suggesting low similarity between the names Merilog and Mebhydroline. Additionally, Mebhydroline is an international drug product marketed in Ukraine and Russia. We note that the proprietary name,

⁹ USAN stem search conducted on August 28, 2024.

Mebhydroline, is not marketed in the United States. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized. We evaluate the name Mebhydroline in Appendix G.

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

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^h identified 110 names with a combined score of $\geq 55\%$ or an individual orthographic or phonetic score of $\geq 70\%$. 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. Therefore, we identified four names not previously analyzed. These names are included in Table 2 below.

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 $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	4
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

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

2.2.8 SAFETY ANALYSIS OF THE PROPOSED MODIFIER, “SOLOSTAR”

The proposed proprietary name, Merilog SoloStar, is comprised of the root name Merilog and the device modifier SoloStar. We note that the SoloStar modifier denotes the specific type of pen injector used for the product that will be packaged as a prefilled pen. This is consistent with the Sanofi brand of approved SoloStar disposable pens (i.e., Admelog SoloStar, Lantus SoloStar,

^h POCA search conducted on September 9, 2024 in version 5.9.

Toujeo SoloStar and Apidra SoloStar). Of note, the device modifier SoloStar was previously reviewed, and we maintain our conclusion that the use of this modifier is appropriate.ⁱ

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On October 22, 2024, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Merilog, is conditionally acceptable.

3.1 COMMENTS TO SANOFI-AVENTIS

We have completed our review of the proposed proprietary names, Merilog and Merilog SoloStar, and have concluded that these proprietary names are conditionally acceptable.

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

ⁱ Mistry, M. Proprietary Name Review Memorandum for (b) (4) SoloStar (IND 133678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Nov 7. PNR ID No. 2018-23010611 and 2018-23072015.

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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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.
 - o 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.

- o 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-

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

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
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	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	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 $\leq 54\%$).

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. Merilog Study (Conducted on 9/6/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Merilog 4 units SQ before each meal</i> <u>Outpatient Prescription:</u> Patient _____ Date _____ Address _____ R <i>Merilog</i> <i>Injection 5 units subcut</i> <i>before each meal</i> <i>#1</i> Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	Merilog Inject 5 units subcutaneously before each meal. Dispense #1.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Merilog	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Merilog					
People Received Study: 190					
People Responded: 86					
Total	20	23	21	22	86
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MARALOG	0	0	5	0	5

MARCLOG	0	0	1	0	1
MARILOG	0	0	4	0	4
MERALOG	0	0	2	0	2
MERILOG	20	22	1	22	65
MERILOG INJECTION	0	1	0	0	1
MIRALOG	0	0	7	0	7
MURALOG	0	0	1	0	1

Figure 2. Merilog SoloStar Study (Conducted on 9/13/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Merilog SoloStar 5 units subQ</i>	Merilog Inject 5 units subcutaneously 5 to 10 minutes before a meal. Dispense #3.
<u>Outpatient Prescription:</u> Patient _____ Date _____ Address _____ R <i>Merilog Solo Star</i> <i>Inject 5 units subQ 5-10 minutes before a meal</i> <i>#3</i>  MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Merilog SoloStar	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Merilog SoloStar					
People Received Study: 187					
People Responded: 84					
Total	22	25	16	21	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MEBHYDROLINE	0	0	0	1	1
MERALOG FILISTAR	0	0	1	0	1
MERALOG SOLOSTAR	0	0	1	0	1
MERILOG	1	1	0	0	2
MERILOG SOLASTAR	1	0	0	0	1
MERILOG SOLO STAR	0	18	0	0	18
MERILOG SOLO START	0	2	0	0	2
MERILOG SOLO STR	0	1	0	0	1
MERILOG SOLOSTAR	8	3	0	20	31
MERILOG SOLSTAR	1	0	0	0	1
MERILOG SOLUSTAR	7	0	0	0	7
MERILOG SOLUSTART	1	0	0	0	1
MEROLOG SOLOSTAR	0	0	1	0	1
MERULOG SOLOSTAR	1	0	0	0	1
MERVILOG SOLOSTAR	1	0	0	0	1
MIRALOG SOLOSTAR	0	0	1	0	1
MOROLOG SOLOSTAR	0	0	1	0	1
MURALOG SOLASTAR	0	0	1	0	1
MURALOG SOLOSTAR	0	0	7	0	7
MURALOR SOOASTAR	0	0	1	0	1
MURILOG SOLISTAR	0	0	1	0	1
MUROLOG SOLOSTAR	0	0	1	0	1
MVULOG SOLOSTAR	1	0	0	0	1

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

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Merilog Pronunciation: Mer-ih-lawg Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Dosage: Individualized dose administered 5 to 10 minutes before a meal	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.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.
2.	Kenalog-40	56	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F. LOW SIMILARITY NAMES (e.g., combined POCA score is $\leq 54\%$) – 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.	Mebhydroline	44	International product marketed in Ukraine and Russia.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion¹

No.	Name	POCA Score (%)
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¹ 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 (%)
1.	(b) (4) ***	59
2.	Proloid	56

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/s/

VRAJ K PATEL
10/25/2024 12:06:09 PM

IDALIA E RYCHLIK
10/25/2024 01:46:37 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:	April 13, 2023
Application Type and Number:	BLA 761325
Product Name and Strength:	(b) (4) (insulin aspart-xxxx) [§] injection, 100 units/mL (b) (4) SoloStar (insulin aspart-xxxx) injection, 100 units/mL
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sanofi-Aventis (Sanofi)
PNR ID #:	2022-1044724757
DMEPA 1 Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDCES
DMEPA 1 Team Leader:	Idalia E. Rychlik, PharmD

[§] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder “insulin aspart-xxxx” is used throughout this review to refer to the nonproprietary name for this product.

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/s/

ARIANE O CONRAD
04/13/2023 04:18:16 PM

IDALIA E RYCHLIK
04/14/2023 04:07:06 AM

MISHALE P MISTRY
04/14/2023 10:49:53 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:	5/4/2023
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761325
Product Name and Strength:	(insulin aspart-szjj) injection 100 units/mL (U-100)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Sanofi-aventis U.S. LLC (Sanofi)
Nexus NPNS ID #:	2022-132
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761325.

1.1 Regulatory History

Sanofi 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

insulin aspart-szjj

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

We determined that the FDA-generated suffix -szjj, 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 3, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on May 4, 2023.

^a Chan, I.Z. General Advice Letter for BLA 761325. Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US) 2022 Oct 18.

^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 FDA-generated suffix -szjj conditionally acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to insulin aspart-szjj. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Sanofi-aventis U.S. LLC

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

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/s/

CARLOS M MENA-GRILLASCA
05/04/2023 05:05:09 PM

IRENE Z CHAN on behalf of MISHALE P MISTRY
05/05/2023 12:16:48 PM
Signed on behalf of Mishale Mistry

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:	August 16, 2023
Application Type and Number:	BLA 761325
Product Name and Strength:	Merilog (insulin aspart-szjj) injection, 100 units/mL Merilog SoloStar (insulin aspart-szjj) injection, 100 units/mL
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sanofi-Aventis (Sanofi)
PNR ID #:	2023-1044725162 and 2023-1044725166
DMEPA 1 Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA 1 Team Leader:	Idalia E. Rychlik, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Merilog and Merilog SoloStar, 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. Sanofi submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Sanofi previously submitted the proposed proprietary names, (b) (4)*** and (b) (4) SoloStar*** under BLA 761325 on September 15, 2022. However, on April 13, 2023, we found the names, (b) (4)*** and (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4).

Thus, Sanofi submitted the names, Merilog and Merilog SoloStar, for review on June 1, 2023 under BLA 761325.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 1, 2023.

- Intended Pronunciation: mer-ih-lawg/mer-ih-lawg soh-loh-stahr
- Nonproprietary Name: insulin aspart-szjj
- Indication of Use: to improve glycemic control in adults and children with diabetes mellitus
- Route of Administration: subcutaneous injection, (b) (4)
(b) (4)
- Dosage Form: injection
- Strength: 100 units/mL
- Dose and Frequency: Individualized dosage based on route of administration, the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal
 - o Subcutaneous injection: Inject within 5-10 minutes before a meal

^a Mistry, M. Proprietary Name Review for (b) (4) (BLA 761325). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 APR 13. PNR ID No. 2022-1044724757.

- How Supplied: 10 mL multiple-dose vial and 3 mL single-patient-use SoloStar prefilled pen
- Storage: Refrigerate between 2°C and 8°C (36°F to 46°F). Do not freeze and do not expose to excessive heat or light.
- Merilog (insulin aspart-szjj) is a proposed biosimilar to US-licensed Reference Product, Novolog (insulin aspart) BLA 020986.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Merilog and Merilog SoloStar.

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*

Sanofi indicated in their submission that the proposed proprietary name, Merilog, is an "insulin analog". We determined that the root name, Merilog, does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

The proposed proprietary name, Merilog SoloStar, is comprised of the root name Merilog and the device modifier SoloStar. We note that the SoloStar modifier denotes the specific type of pen injector used for the product that will be packaged as a prefilled pen. This is consistent with the Sanofi brand of approved SoloStar disposable pens (i.e., Admelog SoloStar, Lantus SoloStar, Toujeo SoloStar and Apidra SoloStar). Of note, the device modifier SoloStar was previously reviewed, and we maintain our conclusion that the use of this modifier is appropriate.^c

^b USAN stem search conducted on June 7, 2023.

^c Mistry, M. Proprietary Name Review Memorandum for (b) (4) SoloStar (IND 133678). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Nov 7. PNR ID No. 2018-23010611 and 2018-23072015.

2.2.3 Comments from Other Review Disciplines at Initial Review

On July 3, 2023, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Merilog and Merilog SoloStar at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (n=90) practitioners participated in DMEPA's prescription studies for Merilog. 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.

Eighty-three (n=83) practitioners participated in DMEPA's prescription studies for Merilog SoloStar. 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.1 contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^d identified 106 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	4
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	116
Low similarity name pair: combined match percentage score $\leq 54\%$	105

^d POCA search conducted on June 7, 2023 in version 5.2.

^e Note (b) (4) also searched POCA for "Merilog Solostar"

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

Our analysis of the 225 names contained in Table 1 determined none of the names will pose a risk for confusion with Merilog as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On August 16, 2023, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary names, Merilog and Merilog Solostar, are 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 SANOFI-AVENTIS

We have completed our review of the proposed proprietary names, Merilog and Merilog Solostar and have concluded that these names are conditionally acceptable.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^f

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

*Table 2- Prescreening Checklist for Proposed Proprietary Name

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

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

- Highly similar pair: combined match percentage score $\geq 70\%$.

- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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 names⁹. 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

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

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 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 $\geq 70\%$).

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.

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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

	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. - Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? - Is there different number or placement of cross-stroke or dotted letters present in the names? - Do the infixes of the name appear dissimilar when scripted? - Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) - Do the names have different number of syllables? - Do the names have different syllabic stresses? - Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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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. Merilog Study (Conducted on July 5, 2023)

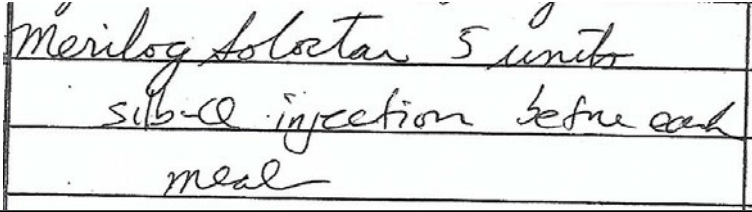
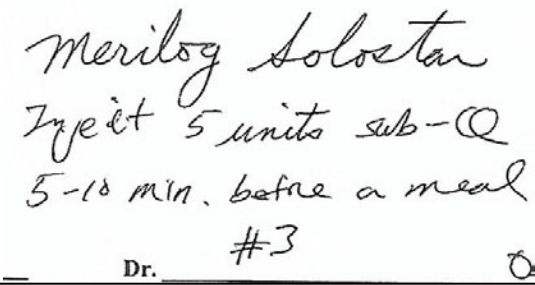
Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Merilog 4 units SQ before each meal</i>	Merilog Inject 5 units subcutaneously before each meal. Dispense #1
<u>Outpatient Prescription:</u> <i>Merilog</i> <i>Inject 5 units subQ before</i> <i>each meal #1</i>	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Merilog	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Merilog					
People Received Study: 254					
People Responded: 90					
Total	21	25	18	26	90
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MARALOG	0	0	4	0	4
MARILOG	0	0	3	0	3
MARILOGUE	0	0	1	0	1
MARYLOG	0	0	1	0	1
MERIALOG	0	0	5	0	5
MERILOG	14	25	1	26	66
MERILOQ	7	0	0	0	7
MIRALOG	0	0	2	0	2
NAIROLOG	0	0	1	0	1

Appendix B.1: Prescription Simulation Samples and Results

Figure 1. Merilog SoloStar Study (Conducted on July 10, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u>  <u>Outpatient Prescription:</u> 	Merilog SoloStar Inject 5 units sub-Q 5 to 10 min. before each meal. Dispense #3.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Merilog SoloStar	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Merilog Solostar - 2023-07-10					
People Received Study: 254					
People Responded: 83					
Total	20	24	16	23	83
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MARALOG SOLOSTAR	0	0	3	0	3
MARILOC SOLOSTAR	0	0	1	0	1
MERALOG SOLASTAR	0	0	2	0	2
MERILOG SOLARTAN	1	0	0	0	1
MERILOG SOLASTAR	0	1	0	0	1
MERILOG SOLOCTAN	1	0	0	0	1

MERILOG SOLOCTAR	1	0	0	0	1
MERILOG SOLORTAR	2	0	0	0	2
MERILOG SOLOSTAN	0	2	0	0	2
MERILOG SOLOSTAR	14	19	4	23	60
MERILOG SOLSTAR	0	1	0	0	1
MERILOQ SOLORTAR	1	0	0	0	1
MEROLOG SOLOSTAR	0	1	0	0	1
MIRALOG SOLARSTAR	0	0	1	0	1
MIRALOG SOLASTAR	0	0	1	0	1
MIRALOG SOLOSTAR	0	0	2	0	2
MUROLOG SOLOSTAR	0	0	1	0	1
MYRALOG SOLOSTAR	0	0	1	0	1

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

No.	Proposed name: Merilog Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Usual Dose: Individualized dose administered 5 to 10 minutes before a meal	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.	Merilog***	100	Subject of this review.
2.	Meriloin	78	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
3.	(b) (4)	74	The first letters of the names ('M' vs. (b) (4) and prefixes of the names differ ('Mer' vs. (b) (4)) which provide for some orthographic differences. The first syllables of the name pair (b) (4) vs. Mer) sound different and Merilog also contains an additional syllable ('ih') which also adds to the name pairs' phonetic difference. The following differences in product characteristics may also help to mitigate the risk of errors: Route of administration: (b) (4) (b) (4) while Merilog can be administered via subcutaneous injection, (b) (4) (b) (4) The route of administration would be specified on a prescription/medication order.
4.	Merolax	70	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Mycolog	62
2.	Marcillin	60
3.	Medrol	60
4.	Marinol	59
5.	Medilax	58
6.	Micrell	58
7.	Perisol	58
8.	Teril	58
9.	Verelan	58
10.	Miraluma	57
11.	Sterilube	57
12.	Midol IB	56
13.	Americet	56
14.	Prilosec	56
15.	Mepriam	56
16.	Amitril	56
17.	Cimerli	56
18.	Migergot	56
19.	Mineral Oil	56
20.	Metrogel	56

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

No.	Proposed name: Merilog Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Usual Dose: Individualized dose administered 5 to 10 minutes before a meal	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.	Virilon	68	The names begin with different letters (M vs. V) and the ending letters differ (g vs. n) which provide some orthographic difference. The first ('mer' vs 'vir') syllables of this name pair provide some phonetic differences.

No.	Proposed name: Merilog Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Usual Dose: Individualized dose administered 5 to 10 minutes before a meal	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
			Virilon is available in capsules for oral administration. Merilog is an injection with patient specific doses as subcutaneous injection before each meal, (b) (4) There is no overlap in dosage form between the products, if included on a prescription/medication order. Furthermore, there is no overlap in route of administration between the products and would need to be specified on a prescription/medication order for Merilog. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
2.	Macrilen	63	This name pair has sufficient orthographic and phonetic differences.
3.	Mio-Rel	62	This name pair has sufficient orthographic and phonetic differences.
4.	Meribin	62	The suffixes provide some orthographic differences (bin vs. log). The last syllables sound different (bin vs. log). Meribin is a dietary supplement available in 5 mg capsules and taken orally as 1 capsule once a day. Merilog is an injection with patient specific doses as subcutaneous injection before each meal, (b) (4) (b) (4) (b) (4) There is no

No.	Proposed name: Merilog Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Usual Dose: Individualized dose administered 5 to 10 minutes before a meal	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
			overlap in dosage form between the products, if included on a prescription/medication order. Furthermore, there is no overlap in route of administration between the products and would need to be specified on a prescription/medication order for Merilog. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
5.	Admelog	61	The prefixes ('Me' vs 'Ad') and the infixes ('ri' vs 'me') of the name pair provide sufficient orthographic differences. This name pair has sufficient phonetic differences.
6.	Novolog	60	The prefixes and infixes ('Meri' vs 'Novo') of this name pair provide sufficient orthographic differences. The first ('mer' vs 'noh') and second ('ih' vs 'voh') syllables of this name pair provide sufficient phonetic differences.
7.	Miralax	60	This name pair has sufficient orthographic and phonetic differences.
8.	Medralone	60	This name pair has sufficient orthographic and phonetic differences.
9.	Medralone 40	60	This name pair has sufficient orthographic and phonetic differences.
10.	Medralone 80	60	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Merilog Established name: insulin aspart-szjj Dosage form: injection Strength(s): 100 units/mL Usual Dose: Individualized dose administered 5 to 10 minutes before a meal	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
11.	Migralex	58	This name pair has sufficient orthographic and phonetic differences.
12.	Ergoloid	58	This name pair has sufficient orthographic and phonetic differences.
13.	Mitrolan	57	his name pair has sufficient orthographic and phonetic differences.
14.	Demerol	56	This name pair has sufficient orthographic and phonetic differences.
15.	Kenalog	56	This name pair has sufficient orthographic and phonetic differences.
16.	Kenalog 40	56	This name pair has sufficient orthographic and phonetic differences.
17.	Kenalog-10	56	This name pair has sufficient orthographic and phonetic differences.
18.	Kenalog-80	56	This name pair has sufficient orthographic and phonetic differences.
19.	Melaleuca	56	This name pair has sufficient orthographic and phonetic differences.
20.	Merilog SoloStar***	50	This name (with the device) is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Enilloring***	54
2.	Menogaril	54
3.	Merisoprol	54
4.	Merolisbac	54
5.	Merrem	54
6.	Metoprolol	54
7.	Humalog	53
8.	Gerimal	52
9.	Metromidol	52
10.	lomeprol	52
11.	Miralaxa	52

No.	Name	POCA Score (%)
12.	Miralimogene	52
13.	(b) (4) **	50
14.	Gimeracil	50
15.	Amilomer	49
16.	Moexipril	48
17.	Meripenem	48
18.	meropenem	48
19.	Ridogrel	48
20.	Rilimogene	48
21.	Tearisol	48
22.	Lime Oil	47
23.	Megestrol	47
24.	Emilimogene	46
25.	Magnalox	46
26.	Mirapex	45
27.	Ergamisol	43
28.	Meradimate	43
29.	Thimerosal	43
30.	Fer-In-Sol Tr	42
31.	Mexiprostil	42
32.	Derisomaltose	40
33.	Enlon	40
34.	Halog	40
35.	Trilostane	40
36.	Rilvegostomig	39
37.	Melengestrol	38
38.	Tridolgosir	38
39.	Molgramostim	36
40.	Orismilast	36
41.	Terrasil Cold Sore	36
42.	Tetramisole	36
43.	Misoprostol	36
44.	Admelog Solostar	35
45.	Ergostat	34
46.	Menostar	34
47.	Mercuric Sulfate	34
48.	Miracle Foot Repair	34
49.	Berotralstat	33
50.	Mercaptopurine	33
51.	Bromo Seltzer	32
52.	Melilotus Extract	32

No.	Name	POCA Score (%)
53.	Nesolicaftor	32
54.	Solosite	32
55.	Sovereign Silver	32
56.	Tri-Lo-Estarylla	32
57.	Umifoxolaner	32
58.	Megestrol Acetate	31
59.	Narlumosbart	31
60.	Nirogacestat	31
61.	Carfloglitazar	30
62.	Mevalonolactone	30
63.	Micellar Otic Cleanser	30
64.	Myristoyl Glutamate	30
65.	Myristyl Acetate	30
66.	Riltovetbart	30
67.	Saroglitazar	30
68.	Uddergold 5 Star	30
69.	Ergoloid Mesylates	29
70.	Apidra Solostar	28
71.	Lirametostat	28
72.	Ricolinostat	28
73.	Sodelglitazar	28
74.	Melengestrol Acetate	26
75.	Osilodrostat	26
76.	Utreloxastat	26
77.	Varoglutamstat	26
78.	Dimer Dilinoleyl Diisostearate	25
79.	Mg217 Psoriasis Coal Tar	25
80.	Diglycol Stearate	24
81.	Elta Seal Moisture Barrier	24
82.	Glyceryl Isostearate	24
83.	Palmitostearate	24
84.	Peg-6 Isostearate	24
85.	Peg-8 Isostearate	24
86.	Tigulixostat	24
87.	Toujeo	24
88.	Toujeo SoloStar	24
89.	Vital-salitar	24
90.	Dexilant Solutab	23
91.	Solostar	23
92.	Triisostearin	23
93.	Decyl Isostearate	22

No.	Name	POCA Score (%)
94.	Toujeo Max SoloStar	22
95.	Trofolastat	22
96.	Isostearyl Isostearate	20
97.	Isostearyl Stearate	20
98.	Lantus SoloStar	20
99.	Pegoxol 7 Stearate	20
100.	Isocetyl Isostearate	19
101.	Vidoflufolastat	18
102.	Apidra	17
103.	Opama	12
104.	Opana	8

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.	Veriloid	69	Brand discontinued with no generic equivalents available. NDA 007336 withdrawn FR effective 06/17/1986.
2.	Meralein	67	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
3.	Moderil	65	Brand discontinued with no generic equivalents available. NDA 010686 withdrawn FR effective 06/18/2009.
4.	Marsilid	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Imbrilon	64	International product marketed in United Kingdom and formerly marketed in Ireland, United Kingdom, and Hong Kong.
6.	Merigolix	64	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
7.	Mino-Lok***	62	Proposed proprietary name for IND 114869 found unacceptable by DMEPA (OSE# 2018-21068091). No new name submitted as of 6/7/2023.
8.	Teril CR	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
9.	Mellaril	62	Brand discontinued with no generic equivalents available. NDA 011808 withdrawn FR effective 12/07/2007.
10.	Mecrilate	62	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
11.	Viril Lam	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Mizollen	60	International product marketed in various countries. International product formerly marketed in various countries.
13.	Mol-Iron	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	M-Eslon	60	International product marketed in Canada, Chile, New Zealand, Turkey, Thailand and formerly marketed in Czech Republic, Hong Kong, and France.
15.	Mellaril-S	60	Brand discontinued with no generic equivalents available. NDA 017923 withdrawn FR effective 12/07/2007.
16.	Mersol	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
17.	Liprolog	60	International product marketed in various countries.
18.	Novalog	60	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
19.	Miradon	59	Brand discontinued with no generic equivalents available. NDA 010909 withdrawn FR effective 12/07/2007.
20.	Migralam	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Vetalog	59	Veterinary product.
22.	Verilopam	59	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
23.	Menrium 10-4	58	Brand discontinued with no generic equivalents available. NDA 014740 withdrawn FR effective 04/26/1996.
24.	Menrium 5-2	58	Brand discontinued with no generic equivalents available. NDA 014740 withdrawn FR effective 04/26/1996.
25.	Menrium 5-4	58	Brand discontinued with no generic equivalents available. NDA 014740 withdrawn FR effective 04/26/1996.
26.	Metryl	58	International product formerly marketed in South Africa.
27.	Merone	58	International product marketed in various countries.
28.	Trilone	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
29.	Dilor-G	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
30.	Melrilimab	58	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
31.	Menrium	58	Brand discontinued with no generic equivalents available. NDA 014740 withdrawn FR effective 04/26/1996.
32.	Merol Sirop	58	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
33.	Moprolol	58	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
34.	Amerifed	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
35.	Peri-D.O.S.	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
36.	Microlite	57	Brand discontinued with no generic equivalents available. BLA 018263 revoked effective 11/02/2020.

No.	Name	POCA Score (%)	Failure preventions
37.	Pyril D	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
38.	Mooredec	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
39.	Marblen	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
40.	Mezlin	56	Brand discontinued with no generic equivalents available. NDA 050549, ANDA 062333, ANDA 062372, and ANDA 062697 withdrawn FR effective 04/04/2005, 10/06/1993, 07/10/2001, and 07/10/2001 respectively.
41.	(b) (4)	56	Brand discontinued with no generic equivalents available. NDA (b) (4) withdrawn FR effective 06/10/1999.
42.	(b) (4)***	56	Proposed proprietary name for BLA 761325 found unacceptable by DMEPA (OSE# (b) (4) dated April 13, 2023). Merilog*** submitted for review, which is the subject of this review.
43.	Metrolyl	56	International product marketed in United Kingdom.
44.	Virilon Im	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
45.	Temaril	56	Veterinary product.
46.	Meridia	56	Brand discontinued with no generic equivalents available. NDA 020632 withdrawn FR Effective 12/21/2010.
47.	(b) (4)***	56	Proposed proprietary name for NDA 211379 found unacceptable by DMEPA (OSE# 2019-28685206 dated April 8, 2019. NDA 211379 approved under the proprietary name, Hemady.
48.	Metrozol	56	International product marketed in various countries.
49.	Regrelor	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
50.	Ericolol	56	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
51.	Meralluride	56	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
52.	Metribolone	56	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
53.	Mineral	56	Product is not a drug. It is a general term. A mineral is a naturally occurring inorganic element or compound having an orderly internal structure and characteristic chemical composition, crystal form, and physical properties.
54.	Xerion	56	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
55.	Marezine	55	Brand discontinued with no generic equivalents available. NDA 009495 withdrawn FR Effective 04/26/1996.
56.	Metreton	55	Product discontinued with no generic equivalents available. ANDA 083834 withdrawn FR effective 12/09/1992.
57.	Myrrh Oil	55	Product is not a drug. It is a plant extract.
58.	Amiprilose	55	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.
59.	Mesilate	55	Product is not a drug. It is a salt or ester of an acid used in pharmaceutical preparations.
60.	Serelis	55	Name identified in external study report. Unable to find product characteristics in commonly used drug databases.

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.	Xermelo	62
2.	(b) (4) ***	60
3.	Boroleum	58
4.	Beryllium	58
5.	Orelox	58
6.	Zerlor	58
7.	Varizig	57
8.	(b) (4) ***	57
9.	Nerolidol	57
10.	Perlite	56
11.	Neurolite	56
12.	Berkolol	56
13.	Normiflo	56
14.	Emetrol	56
15.	Norel Ex	55
16.	Nerol	55
17.	Pergolide	55

^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

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/s/

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