CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761346Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	9/13/2023
Responsible OND Division:	Division of Oncology 1 (DO1)
Application Type and Number:	BLA 761346
Product Name and Strength:	Hercessi (trastuzumab-strf) for injection, 150 mg/vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Accord BioPharma Inc. (Accord)
FDA Received Date:	December 13, 2023
Nexus NPNS ID #:	2022-149
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Accord for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761346.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On December 13, 2023, Accord submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Accord also provided findings from an external study conducted by the (b) (4), evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Accord:

Table 1. Suffixes submitted by Accord***

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

[a] Non-proprietary name suffix BLA 761346. Durham (NC): Accord BioPharma Inc.; 2022 Dec 12. Available from: \\CDSESUB1\EVSPROD\bla761346\0001\m1\us\1124-non-proprietary-name-suffix.pdf

[b] Non-proprietary name report BLA 761346. (b) (4) 2022 Dec 12. Available from: \\CDSESUB1\EVSPROD\bla761346\0001\m1\us\1124-non-proprietary-name-report.pdf

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

2.1 trastuzumab-(b) (4)

Accord's first proposed suffix, (b) (4), is comprised of 4 distinct letters. However, we note that the suffix (b) (4) connotes the word (b) (4) Therefore, we find the proposed suffix, (b) (4), is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

We acknowledge that our evaluation differs from that of the external study performed by the (b) (4) and submitted by the Applicant. In the study conducted by (b) (4), 1 participant in the outpatient verbal prescription simulated study misinterpreted the suffix (b) (4) with a response of (b) (4) However, (b) (4) did not provide further evaluation or comment on the suffix connotation of the word (b) (4).

2.2 trastuzumab-strf

Accord's second proposed suffix, -strf, is comprised of 4 distinct letters. We note that the letters 'tr' and 'rf' in the suffix represent the medical abbreviations for 'time release' and 'reformulation', respectively. We considered whether the inclusion of the letters 'tr' and 'rf' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -strf, 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 2 ANALYSIS

These findings were shared with OPDP. On September 13, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 1 (DO1) on September 13, 2023.

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[a] 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 Accord's proposed suffix -strf acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to trastuzumab-strf. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Accord BioPharma Inc.

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

We also note that the first proposed suffix is unacceptable for the following reason:

1. trastuzumab-(b) (4)

   We note that the suffix (b) (4) connotes the word (b) (4). Therefore, we find the proposed suffix, -(b) (4), is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

   We acknowledge that our evaluation differs from that of the external study performed by the (b) (4) In the study conducted by (b) (4), 1 participant in the outpatient verbal prescription simulated study misinterpreted the suffix (b) (4) with a response of (b) (4). However, (b) (4) did not provide further evaluation or comment on the suffix connotation of the word (b) (4).

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

/s/

CARLOS M MENA-GRILLASCA
09/13/2023 10:30:47 PM

CHI-MING TU
09/14/2023 09:28:38 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	July 3, 2023
Application Type and Number:	BLA 761346
Product Name and Strength:	Hercessi (trastuzumab-xxxx)[a] for Injection, 150 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Accord BioPharma Inc. (Accord)
PNR ID #:	2023-1044725091
DMEPA 2 Safety Evaluator:	Tingting Gao, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

[a] Hercessi has been developed as a proposed biosimilar to US-licensed Herceptin (trastuzumab). Since the nonproprietary name for Hercessi has not yet been determined, "trastuzumab-xxxx" is used throughout this review to refer to the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Accord previously submitted the proposed proprietary name, [redacted]*** under BLA 761346 on December 13, 2022. However, on February 16, 2023, we found the name, [redacted]*** unacceptable due to misbranding concerns.[c]

Thus, Accord submitted the name, Hercessi, for review on April 11, 2023 under BLA 761346.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 11, 2023.

- Intended Pronunciation: her seh' see
- Nonproprietary Name: trastuzumab-xxxx
- Indication of Use:
  - The treatment of HER2-overexpressing breast cancer.
  - The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
- Route of Administration: Intravenous
- Dosage Form: for Injection
- Strength: 150 mg/vial
- Dose and Frequency:
  - Adjuvant treatment of HER2-Overexpressing Breast Cancer (2.2)
  - Administer at either:
    - Initial dose of 4 mg/kg over 90 minute intravenous infusion, then 2 mg/kg over 30 minute intravenous infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Hercessi, administer 6 mg/kg as an IV

[b] Proprietary Name Safety Summary for Hercessi. [redacted] 2023 Mar 22. Available from: \\CDSESUB1\EVSPROD\bla761346\0014\m1\us\118-proprietary-name-report-hercessi.pdf.

[c] Gao, T. Proprietary Name Review for [redacted] (BLA 761346). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 Feb 16. PNR ID No. 2022-1044724885.

infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy, or

- Initial dose of 8 mg/kg over 90 minutes intravenous infusion, then 6 mg/kg over 30 to 90 minutes intravenous infusion every three weeks for 52 weeks.

- Metastatic HER2-Overexpressing Breast Cancer (2.2)
  - Initial dose of 4 mg/kg as a 90 minutes intravenous infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute intravenous infusions.
- Metastatic HER2-Overexpressing Gastric Cancer (2.2)
  - Initial dose of 8 mg/kg over 90 minutes intravenous infusion, followed by 6 mg/kg over 30 to 90 minutes intravenous infusion every 3 weeks.

- How Supplied: Carton contains one single-dose vial
- Storage: Store in refrigerator at 2°C to 8°C (36°F to 46°F)
- Hercessi (trastuzumab-xxxx)] is a proposed biosimilar to US-licensed Reference Product, Herceptin (trastuzumab) BLA 103792.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Hercessi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Hercessi. The Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Hercessi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Accord did not provide a derivation or intended meaning for the proposed proprietary name, Hercessi, in their submission.

[d] USAN stem search conducted on May 23, 2023.

The proposed proprietary name, Hercessi, is comprised of a single word and includes the letter strings, "-er-", an abbreviation for the modifier, "extended release", and the letter strings "-es-", an abbreviation for the modifier "extra strength". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the abbreviation, "er" and "es", in the infix of the name are unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case.

Thus, in this case, we do not object to the inclusion of the letter strings "-er-" and "-es-" in the infix of the proposed proprietary name.

Other than the abbreviation "-er-" and "-es-", the proposed name, Hercessi, does not contain any components (i.e., a modifier, dosage form, etc.) that are misleading or can contribute to medication errors.

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 28, 2023, the Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Hercessi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-four practitioners participated in DMEPA's prescription studies for Hercessi. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 52 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	49

[e] POCA search conducted on May 23, 2023 in version 5.2.

Low similarity name pair: combined match percentage score ≤54%	3

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

Our analysis of the 53 names contained in Table 1 determined none of the names will pose a risk for confusion with Hercessi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On July 3, 2023, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

The proposed proprietary name, Hercessi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO ACCORD BIOPHARMA INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 11, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

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

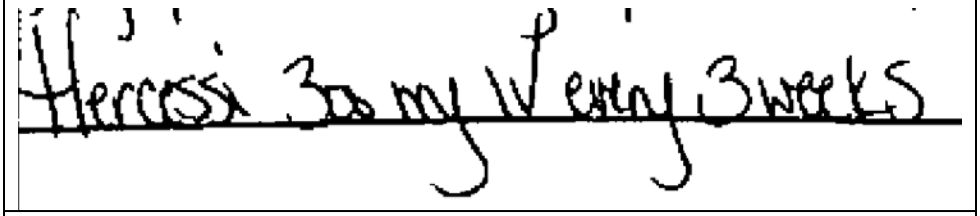
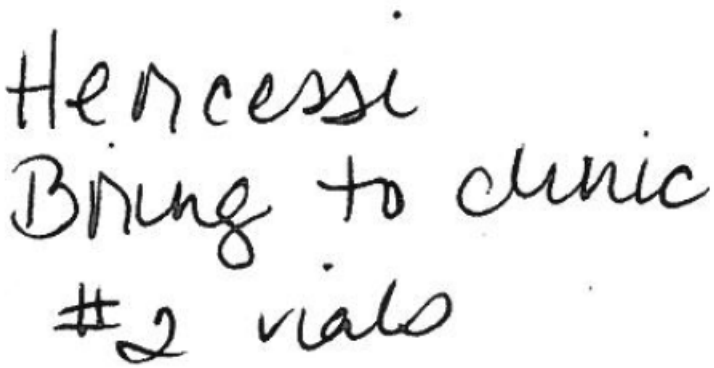
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Hercessi Study (Conducted on April 21, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: 	Hercessi Bring to clinic Dispense two vials
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Hercessi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name:

Hercessi

256 People Received Study

94 People Responded

Total	**22**	**25**	**26**	**21**	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
ERCESSI	0	0	1	0	1
FFERCESSI	1	0	0	0	1
HENCESSI	0	0	0	8	8
HERCESSI	17	25	1	13	56
HERCESSI 30MG	1	0	0	0	1
HERRASSI	1	0	0	0	1
HERRESSI	1	0	0	0	1
HERRSSI	1	0	0	0	1
HERSESHI	0	0	1	0	1
HERSESI	0	0	2	0	2
HERSESSEE	0	0	1	0	1
HERSESSEY	0	0	1	0	1
HERSESSI	0	0	2	0	2
HERSESSY	0	0	1	0	1
MERSESSI	0	0	1	0	1
MERSESSY	0	0	1	0	1
PERCESI	0	0	1	0	1
PERCESSI	0	0	2	0	2
PERCESSY	0	0	2	0	2
PERSECEE	0	0	2	0	2
PERSESI	0	0	3	0	3
PERSESSI	0	0	1	0	1
PERSESY	0	0	1	0	1
VERSESZI	0	0	1	0	1
VIZLYCI	0	0	1	0	1

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

No.	**Proposed name:** Hercessi **Established name:** trastuzumab-xxxx **Dosage form:** for Injection **Strength(s):** 150 mg/vial **Usual Dose:** 2 mg/kg to 8 mg/kg intravenously every 1, 2, or 3 weeks depending on the indication	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.	Hercessi	100	Name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Hypersed	58
2.	Ear-Gesic	57
3.	Hiserpia	57
4.	Thera-Gesic	57
5.	(b) (4) ***	56
6.	Hist-Pse	56
7.	Mircette	56
8.	Quercetin	56

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

No.	**Proposed name:** Hercessi **Established name:** trastuzumab-xxxx **Dosage form:** for Injection **Strength(s):** 150 mg/vial **Usual Dose:** 2 mg/kg to 8 mg/kg intravenously every 1, 2, or 3 weeks depending on the indication	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.	Herceptin	68	Orthographically, Herceptin has a downstroke letter "p" on the 6th position, and an upstroke letter "t" on the 7th position, which is absent in Hercessi. Additionally, the suffixes of the name pair provide sufficient orthographic differences when scripted. Phonetically, the third syllables (see vs. tin) of this name pair sound different when spoken. Hercessi has been developed as a proposed biosimilar to US-licensed Herceptin (trastuzumab). Thus, the risk of harm in the case of a mix-up is likely low. We acknowledge that the proposed name Hercessi begins with the same 5 letters as Herceptin, which raises potential risk for CPOE selection error. However, prescribers already have to select between Herceptin and Herceptin Hylecta from a drug list so this risk of CPOE selection error associated with the "Herce" 5 letters overlap already exists. Thus, we believe the residual risk of CPOE selection error is acceptable in this case.
2.	Her Style	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Hercessi **Established name:** trastuzumab-xxxx **Dosage form:** for Injection **Strength(s):** 150 mg/vial **Usual Dose:** 2 mg/kg to 8 mg/kg intravenously every 1, 2, or 3 weeks depending on the indication	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**
3.	Theracys	62	This name pair has sufficient orthographic and phonetic differences.
4.	Herplex	60	This name pair has sufficient orthographic and phonetic differences.
5.	Cheratussin	59	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
7.	Iressa	57	This name pair has sufficient orthographic and phonetic differences.
8.	Herklin	56	This name pair has sufficient orthographic and phonetic differences.
9.	Herzuma	56	This name pair has sufficient orthographic and phonetic differences.
10.	Histex SR	56	This name pair has sufficient orthographic and phonetic differences.
11.	Hurrisept	56	This name pair has sufficient orthographic and phonetic differences.
12.	Hydrap-ES	56	This name pair has sufficient orthographic and phonetic differences.
13.	Hydrocet	56	This name pair has sufficient orthographic and phonetic differences.
14.	Hydrogesic	56	This name pair has sufficient orthographic and phonetic differences.
15.	Pertussin	56	This name pair has sufficient orthographic and phonetic differences.
16.	Rhopressa	56	This name pair has sufficient orthographic and phonetic differences.
17.	Hisdec	55	This name pair has sufficient orthographic and phonetic differences.
18.	Hypericin	55	This name pair has sufficient orthographic and phonetic differences.
19.	Hyrexin	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Percogesic	52
2.	Sheri-B-12	52
3.	Herbalife	46

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.	Ceresin	66	Product is not a drug. Ceresin is an emulsifier used like a wax to help skincare products, such as pomades and balms, to bind and maintain their consistencies.
2.	(b) (4) ***	63	Proposed proprietary name for IND 127416 found unacceptable by DMEPA (OSE# 2016-8524628). NDA 209394 approved under the proprietary name Mavyret.
3.	Herpid	63	International product formerly marketed in the United Kingdom.
4.	(b) (4) ***	61	Proposed proprietary name for BLA 761346 found unacceptable by DMEPA (OSE# 2022-1044724885). The Applicant submitted a new proposed proprietary name, Hercessi, for BLA 761346, which is the subject of this review.
5.	Sericin 1	61	Product is not a drug. It is a protein found in silkworm cocoons.
6.	Helicin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	(b) (4) ***	57	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4)). The Sponsor subsequently submitted new proprietary names, (b) (4) *** and (b) (4) ***, both names were withdrawn, and there are no new names proposed for IND (b) (4) Additionally, IND (b) (4) is currently in Full Clinical Hold status since (b) (4)
8.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4). IND (b) (4) is conditionally approved under the proprietary name, (b) (4) ***.

No.	Name	POCA Score (%)	Failure preventions
9.	(b) (4)***	56	Proposed proprietary name for BLA (b) (4) found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). BLA (b) (4) is conditionally approved under the proprietary name (b) (4). However, BLA (b) (4) is in Complete Response status since (b) (4)

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.	Certuss	60
2.	Serpasil	59
3.	Certiva	58
4.	Erycette	58
5.	Ser-Ap-Es	58
6.	Verdeso	58
7.	Arsenic	56
8.	(b) (4)***	56
9.	Perseris	56
10.	Refissa	56
11.	Servira	56
12.	Veraciti	56
13.	Serpex	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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