

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

219293Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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

Date of This Review:	April 26, 2024
Application Type and Number:	NDA 219293
Product Name, Dosage Form, and Strength:	Danziten (nilotinib) Tablets, 71 mg and 95 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Slayback Pharma LLC (Slayback)
PNR ID #:	2024-1044725600
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature & Labeling:	Hina Mehta, PharmD

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1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 30, 2024^a, and the prescribing information received on January 30, 2024^b.

Table 1. Relevant Product Information for Danziten	
Intended pronunciation:	dan-zit-en
Active ingredient:	nilotinib
Indication:	- Adult Patients With Newly Diagnosed Ph+ CML-CP Indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. - Adult Patients With Resistant or Intolerant Ph+ CML-CP and CML-AP Indicated for the treatment of adult patients with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) resistant or intolerant to prior therapy that included imatinib.
Dosage Form:	Tablets
Strength:	71 mg and 95 mg
Route of administration:	Oral

^a Request for Proprietary Name Review for Danziten (NDA 219293). Princeton (NJ): Slayback Pharma LLC; 2024 JAN 30. Available from: <\\CDSESUB1\EVSPROD\nda219293\0002\m1\us\118-prop-name-rev-req-danziten.pdf>.

^b Proposed prescribing information for Danziten. Princeton (NJ): Slayback Pharma LLC; 2024 Jan 30. Available from: <\\CDSESUB1\EVSPROD\nda219293\0001\m1\us\prescribing-information-label.pdf>.

Table 1. Relevant Product Information for Danziten	
Usual dosage and frequency:	• Dosage in Adult Patients with Newly Diagnosed Ph+ CML-CP The recommended dosage is 142 mg orally twice daily with or without food. • Dosage in Adult Patients with Resistant or Intolerant Ph+ CML-CP and CML-AP The recommended dosage is 190 mg orally twice daily with or without food. • Dose modifications: ○ 190 mg once daily ○ 142 mg once daily ○ 95 mg twice daily ○ 95 mg once daily
How Supplied:	TRADENAME (nilotinib) 71 mg tablets are pink, coated, oblong tablets, debossed with “N5” on one side and plain on other side. TRADENAME (nilotinib) 95 mg tablets are yellow, coated, oblong tablets, debossed with “N2” on one side and plain on other side. TRADENAME (nilotinib) 71 mg and 95 mg tablets are supplied in blister packs. • 71 mg Outer Carton of 4 (b) (4) packs of (4x28) (b) (4) of 2 blister packs (2x14) Blisters of 14 tablets (1x14) • 95 mg Outer Carton of 4 (b) (4) packs of (4x28) (b) (4) of 2 blister packs (2x14) Blisters of 14 tablets (1x14)
Storage:	TRADENAME (nilotinib) tablets should be stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].
Listed Drug:	Tasigna (nilotinib) capsules NDA 022068

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Danziten 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 Danziten. The Division of Hematologic Malignancies 1 (DHM 1) did not comment on the findings of OPDP’s assessment for Danziten.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On March 6, 2024, the Division of Hematologic Malignancies 1 (DHM 1) did not forward any comments or concerns relating to Danziten at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

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

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^d identified 494 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names

^c USAN stem search conducted on January 31, 2024.
^d POCA search conducted on January 31, 2024 in version 5.5.

Highly similar name pair: combined match percentage score $\geq 70\%$	5
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	480
Low similarity name pair: combined match percentage score $\leq 54\%$	9

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

Our analysis of the 494 names contained in Table 2 determined none of the names will pose a risk for confusion with Danziten as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 26, 2024, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 1 (DHM 1).

3 CONCLUSION

The proposed proprietary name, Danziten, is conditionally acceptable.

If you have any questions or need clarifications, please contact Candido Alicea, OSE project manager, at 240-402-8310.

3.1 COMMENTS TO SLAYBACK PHARMA LLC

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

If any of the proposed product characteristics as stated in your submission, received on January 30, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

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

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

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

Drugs@FDA

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

RxNorm

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

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

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

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

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

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

*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.

^e 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^f. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- 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-

^f 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 $\leq 69\%$).

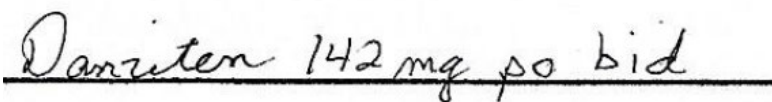
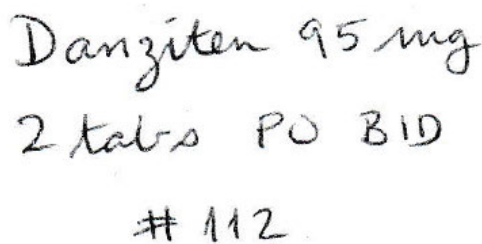
	placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	
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Table 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. Danziten Study (Conducted on 2/9/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> 	Danziten 95 mg Two tablets by mouth twice daily Dispense 112
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Danziten	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Danziten					
People Received Study: 165					
People Responded: 78					
Total					
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
DANRITEN	1	0	0	0	1
DANZATEN	0	0	3	0	3
DANZITAN	0	0	1	0	1
DANZITEM	0	1	0	0	1
DANZITEN	16	21	1	23	61
DANZITIN	0	0	1	0	1
DARZETAN	1	0	0	0	1
DAZINTEN	0	0	1	0	1
DEANZATEN	0	0	1	0	1
DEENZITEN	0	0	1	0	1

DEINZATIM	0	0	1	0	1
DEINZETEN	0	0	1	0	1
DENZATEN	0	0	1	0	1
DIANZATAM	0	0	1	0	1
DIANZATEN	0	0	1	0	1
DIENZATEN	0	0	1	0	1

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

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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.	Danziten	100	This name is the subject of this review.
2.	Zaditen	76	International product marketed in the United Kingdom, Canada, Singapore, France, Italy, Portugal, Hong Kong, Indonesia, Japan, Malaysia, Mexico, New Zealand, South Africa, Switzerland, Thailand, Turkey, Venezuela, Germany, Norway, Spain, and Brazil and formerly marketed in Argentina, Australia, Chile, Russia, and Ukraine.
3.	Benzapen	74	International product marketed in Turkey and formerly marketed in Brazil.
4.	Manzatin-E	72	Orthographically, the dotted letter “i” is in different locations within each name (5th vs. 7th position). Additionally, Manzatin-E contains the modifier “-E”, which, if included, serves to provide more visual difference between the pairs. Phonetically, the beginning of the first syllables (Dan vs. Man), ending of second syllables (zit vs. za), and the beginning of the third syllables (en vs. tin) provides some phonetic differences. Additionally, Manzatin-E contains the modifier “-E”, which, if spoken, serves to provide additional phonetic difference. There is no direct overlap in strength (71 mg and 95 mg vs. 18%) and since Danziten is available in multiple strengths, a strength must be provided on a prescription. This name pair also differs

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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.
			in dosage form (tablet vs. ointment), route (oral vs. topical), dose (142 mg, 190 mg, 95 mg, 1 tablet, or 2 tablets vs. a thin layer), and frequency (once or twice daily vs. as necessary with each diaper change or when exposure to wet diapers may be prolonged). Thus, in this case, the risk of name confusion between this name pair is minimized.
5.	Panretin	71	Orthographically, this name pair have the dotted letter “i” in different locations within each name (5th vs. 7th position). Additionally, Danziten contains the letter optional downstroke ‘z’ in the fifth position and if scripted with the downstroke it could provide additional difference. Phonetically, the beginning of the first syllable (Dan vs. Pan) and the second syllables (zit vs. reh) sound different. Although there is direct overlap in frequency (twice daily), the name pair differs in dosage form (tablet vs. gel), route (oral vs. topical), dose (142 mg, 190 mg, 95 mg, 1 tablet, or 2 tablets vs. a generous coating), and strength (71 mg and 95 mg vs. 0.1%), where the strength would need to be specified on an order for Danziten.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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.
			Thus, in this case, the risk of name confusion between this name pair is minimized.

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.	Benzaclin	66
2.	Benzene	66
3.	Dermazene	62
4.	Delazinc	61
5.	Tungsten	61
6.	Dawnzera***	60
7.	Dermacin	60
8.	Dextran	59
9.	Dextran 1	59
10.	Dextran 110	59
11.	Dextran 40	59
12.	Dextran 70	59
13.	Dextran 75	59
14.	Digisan	59
15.	End-Zit	59
16.	Dexacine	58
17.	Tazarotene	58
18.	Dentagel	57
19.	Disotate	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: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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.	Desitin	69	Orthographically, the infixes differ. Specifically, Desitin contains an additional dotted letter (i) in the infix. Danziten also contains a z in the infix, which gives some visual difference. In some cases, the letter z may be scripted with a downstroke, which can further help differentiate the name pairs by giving them different shapes. Phonetically, the ending of the first syllable (Dan vs. De) provide some difference. This name pair differ in dosage form (tablet vs. cream, paste, and ointment), route (oral vs. topical), dose (142 mg, 190 mg, 95 mg, 2 tablets, or 1 tablet vs. apply a generous layer), and frequency (twice daily vs. apply as often as necessary with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged). When all of the aforementioned factors are considered in totality, we find the risk of name confusion between the name pair is adequately minimized in this case.
2.	Dandrene	68	This name pair has sufficient orthographic and phonetic differences.
3.	Benzodent	66	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
4.	(b) (4) ***	66	This name pair has sufficient orthographic and phonetic differences.
5.	Dermatin	66	Orthographically, the dotted letter (i) is in different locations within the name pair (5th vs. 7th position). Danziten also contains a z in the infix, which, in some cases, may be scripted with a downstroke, which can further help differentiate the name pairs by giving them different shapes. Phonetically, the ending of the first (Dan vs. Dur) and second (zit vs. ma) syllables sound different. There is no direct overlap in strength (71 mg and 95 mg vs. 1%), and since Danziten is available in multiple strengths a strength must be provided on a prescription. Additionally, there is no direct overlap in dosage form (tablet vs. cream), route (oral vs. topical), and dose (142 mg, 190 mg, 95 mg, 2 tablets, or 1 tablet vs. apply a thin layer). When all of the aforementioned factors are considered in totality, we find the risk of name confusion between the name pair is adequately minimized in this case.
6.	Dexacen-4	66	This name pair has sufficient orthographic differences. Phonetically, the ending of the first syllable (Dan vs. Dex) and second syllable

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
			(zit vs. ah) sound different. Additionally, Dexacen-4 contains the modifier 4 which is an extra syllable. Although there is numerical similarity in dose (1 tablet vs. 1 mg), the name pair differ in dosage form (tablet vs. injection), strength (71 mg and 95 mg vs. 4 mg/mL and 20 mg/5 mL (4 mg/mL)) and route (oral vs. intravenous or intramuscular). Thus, in this specific case, the risk of name confusion between this name pair is minimized.
7.	Bendectin	65	This name pair has sufficient orthographic differences. Phonetically, the beginning of the first syllable (Dan vs. Ben) and the second syllable (zit vs. dec) sound different. There is no direct overlap in strength (71 mg and 95 mg vs. 10 mg/10 mg and 20 mg/20 mg), and since both products are available in multiple strengths a strength must be provided on a prescription. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
8.	Dent-O-Kain	65	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
9.	Dilantin	65	This name pair has sufficient orthographic and phonetic differences.
10.	Dilantin-125	65	This name pair has sufficient orthographic and phonetic differences.
11.	Dilantin-30	65	This name pair has sufficient orthographic and phonetic differences.
12.	Datscan	64	This name pair has sufficient orthographic and phonetic differences.
13.	Dynapen	64	This name pair has sufficient orthographic and phonetic differences.
14.	Loniten	64	Orthographically, this name pair begin with differently shaped letters (D vs. L). Additionally, Danziten contains a z in the infix, which gives some visual difference. In some cases, the letter z may be scripted with a downstroke, which can further help differentiate the name pairs by giving them different shapes. This name pair has sufficient phonetic differences. There is no direct overlap in strength (71 mg and 95 mg vs. 2.5 mg and 10 mg), and since both products are available in multiple strengths a strength would need to be specified on a prescription. Thus, in this case, the risk of name confusion between this name pair is minimized.
15.	Benzacot	63	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	Ditropan	63	This name pair has sufficient orthographic and phonetic differences.
17.	Anzemet	62	This name pair has sufficient orthographic and phonetic differences.
18.	Diazepam	62	This name pair has sufficient orthographic and phonetic differences.
19.	Dimaphen	62	This name pair has sufficient orthographic and phonetic differences.
20.	Doxidan	62	This name pair has sufficient orthographic and phonetic differences.
21.	Dynacin	62	This name pair has sufficient orthographic and phonetic differences.
22.	Maintena***	62	This name pair has sufficient orthographic and phonetic differences. Additionally, it is a modifier associated with an Abilify product.
23.	Nintedanib	62	This name pair has sufficient orthographic and phonetic differences.
24.	Panmycin	62	This name pair has sufficient orthographic and phonetic differences.
25.	Teveten	62	This name pair has sufficient orthographic and phonetic differences.
26.	Dextenza	61	This name pair has sufficient orthographic and phonetic differences.
27.	Donnapine	61	This name pair has sufficient orthographic and phonetic differences.
28.	Doxepin	61	This name pair has sufficient orthographic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
			Phonetically, the ending of the first syllable (Dan vs. Docks) and second (zit vs. ah) syllable sound different. Although Daziten and Doxepin overlap in dose (1 tab), the name pair differ in strength (71 mg and 95 mg vs. 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 10 mg/mL, 3 mg, 6 mg, and 5%), and since both products are available in multiple strengths a strength would need to be specified on an order. Thus, in this case, the risk of name confusion between this name pair is minimized.
29.	Aplenzin	60	This name pair has sufficient orthographic and phonetic differences.
30.	Dabigatran	60	This name pair has sufficient orthographic and phonetic differences.
31.	Dandrex	60	This name pair has sufficient orthographic and phonetic differences.
32.	Denticare	60	This name pair has sufficient orthographic and phonetic differences.
33.	Donnaphen	60	This name pair has sufficient orthographic and phonetic differences.
34.	Lindane	60	This name pair has sufficient orthographic and phonetic differences.
35.	Delaxin	59	This name pair has sufficient orthographic and phonetic differences.
36.	Benzac Ac	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
37.	Dantrium	58	This name pair has sufficient orthographic and phonetic differences.
38.	Daranide	58	This name pair has sufficient orthographic and phonetic differences.
39.	Dasatinib	58	This name pair has sufficient orthographic and phonetic differences.
40.	Dawnmist	62	This name pair has sufficient orthographic and phonetic differences.
41.	D-Biotin	58	This name pair has sufficient orthographic and phonetic differences.
42.	Delalutin	58	This name pair has sufficient orthographic and phonetic differences.
43.	Dendrid	58	This name pair has sufficient orthographic and phonetic differences.
44.	Digitek	58	This name pair has sufficient orthographic and phonetic differences.
45.	Dimetapp Nd	58	This name pair has sufficient orthographic and phonetic differences.
46.	Dralzine	58	This name pair has sufficient orthographic and phonetic differences.
47.	Dristan	58	This name pair has sufficient orthographic and phonetic differences.
48.	Endodan	58	This name pair has sufficient orthographic and phonetic differences.
49.	Gamastan	58	This name pair has sufficient orthographic and phonetic differences.
50.	Gendecon	58	This name pair has sufficient orthographic and phonetic differences.
51.	Nizatidine	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
52.	Olanzapine	58	This name pair has sufficient orthographic and phonetic differences.
53.	Ondansetron	58	This name pair has sufficient orthographic and phonetic differences.
54.	Stanozide	58	This name pair has sufficient orthographic and phonetic differences.
55.	Tensilon	58	This name pair has sufficient orthographic and phonetic differences.
56.	Tizanidine	58	This name pair has sufficient orthographic and phonetic differences.
57.	Clenziderm	57	This name pair has sufficient orthographic and phonetic differences.
58.	Dalteparin	57	This name pair has sufficient orthographic and phonetic differences.
59.	Danocrine	57	This name pair has sufficient orthographic and phonetic differences.
60.	Dantrolene	57	This name pair has sufficient orthographic and phonetic differences.
61.	Deltalin	57	This name pair has sufficient orthographic and phonetic differences.
62.	Dermazinc	57	This name pair has sufficient orthographic and phonetic differences.
63.	Dexacidin	57	This name pair has sufficient orthographic and phonetic differences.
64.	Dexilant	57	This name pair has sufficient orthographic and phonetic differences.
65.	Didanosine	57	This name pair has sufficient orthographic and phonetic differences.
66.	Diphentann D	57	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Danziten Established name: nilotinib Dosage form: Tablets Strength(s): 71 mg and 95 mg Usual dose: 142 mg orally twice daily or 190 mg orally twice daily.	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
67.	Duration	57	This name pair has sufficient orthographic and phonetic differences.
68.	Zincate	57	This name pair has sufficient orthographic and phonetic differences.
69.	Azacididine	56	This name pair has sufficient orthographic and phonetic differences.
70.	Dapsone	56	This name pair has sufficient orthographic and phonetic differences.
71.	Delta-Lutin	56	This name pair has sufficient orthographic and phonetic differences.
72.	Depakene	56	This name pair has sufficient orthographic and phonetic differences.
73.	Diprivan	56	This name pair has sufficient orthographic and phonetic differences.
74.	Doxazosin	56	This name pair has sufficient orthographic and phonetic differences.
75.	Dynafed	56	This name pair has sufficient orthographic and phonetic differences.
76.	Macitentan	56	This name pair has sufficient orthographic and phonetic differences.
77.	Arthriten	55	This name pair has sufficient orthographic and phonetic differences.
78.	Capoten	55	This name pair has sufficient orthographic and phonetic differences.
79.	Dipentum	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.	Adenine	54

No.	Name	POCA Score (%)
2.	Atazine	54
3.	Ganite	54
4.	Indanazoline	54
5.	Dyazide	53
6.	Azasite	52
7.	Iodate Ion	51
8.	Radiant White	46
9.	Aconite	44

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

No.	Name	POCA Score (%)	Failure preventions
1.	Demazin	69	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. Additionally, this name corresponds to the root name of an international product line of cough and cold products some of which are currently marketed in Australia and New Zealand, and some which are formerly marketed in Australia, South Africa, and New Zealand.
2.	Antiben	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. Additionally, this name is an international product marketed in Mexico.
3.	Canesten	68	International product marketed in Australia, Austria, Brazil, Canada, Chile, Czech Republic, Denmark, Finland, Germany, Greece, Hong Kong, Hungary, India, Ireland, Israel, Italy, Malaysia, New Zealand, the Netherlands, Norway, Philippines, Portugal, Russia, South Africa, Singapore, Sweden, Switzerland, Turkey, Ukraine, Venezuela, and formerly marketed in Poland.
4.	Dimetane	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are

No.	Name	POCA Score (%)	Failure preventions
			available. NDA 010799 withdrawn FR effective June 16, 2006.
5.	Dibenzepin	67	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Antatens	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Moditen	66	International product marketed in Italy, Venezuela, Hungary, Russia, and Ukraine and formerly marketed in Ireland, Czech Republic, the Netherlands, and France.
8.	Angitate	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Condasin	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	Dimetane-Ten	64	Brand discontinued with no generic equivalents available. NDA 011418 withdrawn FR effective 09/17/2003.
11.	Tenkicin	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Diphentann	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Migraten	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Antisedan	62	Veterinary product.
15.	Benzie Pak	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Danthron	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
17.	Dentapaine	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
18.	Genticin	62	International product marketed in Ireland and the United Kingdom.
19.	Ivadantin	62	Brand discontinued with no generic equivalents available. NDA 012402 withdrawn FR effective 09/29/1995.
20.	Vasaten	62	International product formerly marketed in Venezuela.
21.	Doxatet	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Varenzin	61	Veterinary product.
23.	Dalacin T	60	International product marketed in Australia, Brazil, Chile, China, Hong Kong, Ireland, Italy, Malaysia, Mexico, Poland, Portugal, Singapore, Switzerland, Thailand, and the UK, and formerly marketed in Hungary, Netherlands, and South Africa.
24.	Daricon	60	Brand discontinued with no generic equivalents available. NDA 011612 withdrawn FR effective 09/22/1999.
25.	Denti Care	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Dezocine	60	Brand discontinued with no generic equivalents available. NDA 019082 withdrawn FR effective 09/30/2000.
27.	Disadine	60	International product formerly marketed in the United Kingdom and Ireland as Disadine DP.
28.	Domiphen	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
29.	Doriden	60	Brand discontinued with no generic equivalents available. NDA 009519 withdrawn FR effective 04/26/1996.
30.	Dynaxin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Montephen	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
32.	Ranitidine	60	All prescription and nonprescription ranitidine containing medications have been withdrawn from the U.S. market as of April 1, 2020 because of concerns over levels of the contaminant N-nitrosodimethylamine (NDMA).
33.	Tanzeum	60	Brand discontinued with no generic equivalents available. BLA 125431 voluntarily revoked effective 10/23/2020.
34.	Vetripin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Duratan	59	Name identified in RxNorm database. Root name for Duratan DM, Durtan Forte, and Duratan PE. Product line is deactivated and no generic equivalents are available.
36.	Atensine	58	International product formerly marketed in Ireland and the United Kingdom.
37.	Azintamide	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Combi-Pen-48	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Daktarin	58	International product marketed in Australia, Belgium, Brazil, Finland, France, Israel, Mexico, Netherlands, Thailand, Venezuela, and many other countries.

No.	Name	POCA Score (%)	Failure preventions
40.	(b) (4) ***	58	Proposed proprietary name for IND 129198 and BLA 761127 and found unacceptable by DMEPA (2019-33884038 and OSE#2019-35994384 dated 02/21/2020) due to similarity with marketed and discontinued products. BLA 761127 approved under the proprietary name Daxxify.
41.	Dentipatch	58	Brand discontinued with no generic equivalents available. NDA 020575 withdrawn FR effective 11/03/2016.
42.	Diosmetin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
43.	Ditate-Ds	58	Brand discontinued with no generic equivalents available. ANDA 086423 withdrawn FR effective 01/24/1989.
44.	Dodicin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Donnazyme	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. Additionally, product is an international product formerly marketed in Canada.
46.	Gondafon	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Minitec	58	Brand discontinued with no generic equivalents available. NDA 017339 withdrawn FR effective 03/13/2009.
48.	Nitrite Ion	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Pondimin	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
50.	Ponstan	58	International product marketed in several countries including the United Kingdom,

No.	Name	POCA Score (%)	Failure preventions
			Australia, Brazil, Greece, Hong Kong, Mexico, Portugal, and South Africa, and many other countries.
51.	Tenathan	58	Brand discontinued with no generic equivalents available. NDA 017675 withdrawn FR effective 09/04/1996.
52.	Tridane	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	1,9-Decadiene	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
54.	Anisate	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	Decazate	57	International product formerly marketed in the United Kingdom.
56.	Delaquin	57	Veterinary Product.
57.	Detane	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. Additionally, product is an international product formerly marketed in Canada.
58.	Dexased	57	Veterinary product.
59.	Dibekacin	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Tempo Pen***	57	Name identified in Name Entered by Safety Evaluator. Product is not a drug. "Tempo Pen" is a modifier used to modify the proprietary names Lyumjev, Humalog and Basaglar (Lyumjev Tempo Pen, Humalog Tempo Pen, and Basaglar Tempo Pen). We would not expect the modifier "Tempo Pen" to be used without the root names.
61.	Azatadine	56	Name identified in RxNorm database. Per Redbook, product was available as Azatadine

No.	Name	POCA Score (%)	Failure preventions
			maleate. Product is deactivated and no generic equivalents are available.
62.	Benziq	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
63.	Dacabazine	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
64.	D-Amine	56	Name identified in RxNorm database. Per Redbook, product was available as D-Amine-SR. Product is deactivated and no generic equivalents are available.
65.	Darvocet-N 100	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
66.	Darvocet-N 50	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
67.	Dentomycin	56	International product formerly marketed in the United Kingdom, Ireland, and Germany.
68.	Deprizine	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
69.	Dermaseptin	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
70.	Detussin	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
71.	Dexasone	56	Veterinary product.
72.	Digitalin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Dimetane Dc	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
74.	Dimethindene	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Dioxane	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
76.	Dodatate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
77.	Dothiepin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
78.	Droncit	56	Veterinary Product.
79.	Hydantoin	56	Product is not a drug. It is a class of anticonvulsant.
80.	Nitetime	56	Product is not a drug. It is modifier or descriptor used with multiple cough and cold products with which the formulation would need to be specified to dispense.
81.	Benziq Ls	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
82.	Canesten Af	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
83.	Denatonium	55	Product is not a drug. It is a bittering agent to prevent accidental swallowing by children.
84.	Denaverine	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
85.	Dexatrim	55	Name identified in RxNorm database. Root name for product that contained phenylpropanolamine which is deactivated with no generic equivalents available.
86.	Diatensec	55	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
87.	Digiter	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
88.	Disofenin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
89.	Magnesite	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
90.	Tensium	55	International product marketed in Argentina and the United Kingdom.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion⁹.

No.	Name	POCA Score (%)
1.	Fentazin	66
2.	Antepsin	65
3.	Pediatan	65
4.	Benzoin	64
5.	Mantadine	64
6.	Tannate 12D S	64
7.	Zenatane	64
8.	Zenzedi	64
9.	Anthisan	63
10.	Mentadent	63
11.	Acitretin	62
12.	Epanutin	62
13.	Ganidin Nr	62
14.	Gantrisin	62
15.	Gavilyte-N	62

⁹ 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 (%)
16.	Jantoven	62
17.	Naturetin	62
18.	Naturetin-10	62
19.	Naturetin-2.5	62
20.	Naturetin-5	62
21.	Nitrotan	62
22.	Painzone	62
23.	Penbritin	62
24.	Sandimmune	62
25.	Santonin	62
26.	Tazidime	62
27.	Tedrigen	62
28.	Vandetanib	62
29.	Vantin	62
30.	Indican	61
31.	Kinetin	61
32.	Advantame	60
33.	Akineton	60
34.	Banthine	60
35.	Benzedrine	60
36.	Benzonate	60
37.	Benztrone	60
38.	Bronitin	60
39.	Bunazosin	60
40.	Candin	60
41.	Carnitine	60
42.	Cenestin	60
43.	Genistein	60
44.	Idamycin	60
45.	Magnapen	60
46.	Mangimin	60
47.	Maxiphen	60

No.	Name	POCA Score (%)
48.	Medipain 5	60
49.	Minitran	60
50.	(b) (4) ***	60
51.	Nydrazid	60
52.	Pagitane	60
53.	Pantethine	60
54.	Pediatan D	60
55.	Pentazine	60
56.	Phenacetin	60
57.	Phenzone	60
58.	Principen	60
59.	Principen '125'	60
60.	Principen '250'	60
61.	Principen '500'	60
62.	Tadenan	60
63.	Tanabid	60
64.	Tanafed	60
65.	Tandem Ob	60
66.	Tannate 12 S	60
67.	Timentin	60
68.	Tinzaparin	60
69.	Vancocin	60
70.	Vetmedin	60
71.	Xenazine	60
72.	Zinc Cation	60
73.	Ancestim	59
74.	Ben Tann	59
75.	Benzamycin	59
76.	Benzoate	59
77.	Genaton	59
78.	Manidipine	59
79.	Midol Teen	59

No.	Name	POCA Score (%)
80.	Prandimet	59
81.	Tinactin	59
82.	Trandate	59
83.	Undecane	59
84.	Xanthine	59
85.	(b) (4) ***	58
86.	Amantadine	58
87.	Ampitrin	58
88.	Amsidine	58
89.	Asendin	58
90.	Bamethan	58
91.	Banophen	58
92.	Benzefoam	58
93.	Benzocaine	58
94.	Bynfezia Pen	58
95.	Cancidas	58
96.	Candee Caine	58
97.	Centussin	58
98.	Clindacin	58
99.	Endafed	58
100.	Gelatin	58
101.	Genestin	58
102.	Gentisate	58
103.	Junifen	58
104.	Kenocidin	58
105.	Kentiazem	58
106.	Laniazid	58
107.	Lanozin	58
108.	Medazepam	58
109.	Med-I-San	58
110.	Nitrate Ion	58
111.	Nystatin	58

No.	Name	POCA Score (%)
112.	Pancreatin	58
113.	Pediaphen	58
114.	Pentetate	58
115.	Pitressin	58
116.	Renacidin	58
117.	Tab Tussin	58
118.	Tanabid Da	58
119.	Tanamine	58
120.	Tandem	58
121.	Targretin	58
122.	Tazicef	58
123.	Temazepam	58
124.	Tetracyn	58
125.	Trandide	58
126.	Uni-Tren	58
127.	Vindesine	58
128.	Zadstat	58
129.	Zanidip	58
130.	Zarontin	58
131.	Zeatin	58
132.	Zeniquin	58
133.	Zilactin	58
134.	Zonisade	58
135.	Aconitine	57
136.	(b) (4) ***	57
137.	Amnesteem	57
138.	(b) (4) ***	57
139.	Antisept	57
140.	Antitussin	57
141.	Apsifen	57
142.	Balgifen	57
143.	Banadyne	57

No.	Name	POCA Score (%)
144.	Benzydamine	57
145.	Bimectin	57
146.	Catechin	57
147.	Gentaved	57
148.	Gentaved 100	57
149.	(b) (4) ***	57
150.	Medipren	57
151.	Nazarin	57
152.	Nitrogen	57
153.	Setlakin	57
154.	Tamoxifen	57
155.	Tannate Pd-Dm	57
156.	Terazosin	57
157.	Tridrane	57
158.	Uni-Tann	57
159.	Zinecard	57
160.	Adapin	56
161.	Advocin	56
162.	Adzenys	56
163.	Amineptin	56
164.	Amitone	56
165.	Anacin	56
166.	Angiozem	56
167.	Antacid I	56
168.	Bamipine	56
169.	Banamine	56
170.	Banocide	56
171.	Benzonatate	56
172.	Bepadin	56
173.	Capzasin-P	56
174.	Cidacin	56
175.	Claritin	56

No.	Name	POCA Score (%)
176.	Contimin	56
177.	Edurant Ped***	56
178.	Elantan	56
179.	Entaprin	56
180.	Epaned Kit	56
181.	Fisetin	56
182.	Gadavist	56
183.	Gentacidin	56
184.	Gentamed	56
185.	(b) (4) ***	56
186.	Guanidine	56
187.	Ibumetin	56
188.	Kanjinti	56
189.	Lasmiditan	56
190.	Lidazone	56
191.	Lidifen	56
192.	Magnebind	56
193.	Magnebind 250/300	56
194.	Magnebind 400/200	56
195.	Magnebind-200	56
196.	Magnebind-300	56
197.	Mangiferin	56
198.	Mangostin	56
199.	Mantadil	56
200.	Maxifed	56
201.	Medcodin	56
202.	Metreton	56
203.	Metrodin	56
204.	Mianserin	56
205.	Minizide	56
206.	Naftin	56
207.	N-Dodecane	56

No.	Name	POCA Score (%)
208.	Neocidin	56
209.	Nitrazepam	56
210.	Nordazepam	56
211.	Omnipen	56
212.	Omnipen-N	56
213.	Pacifene	56
214.	Pacitron	56
215.	(b) (4) ***	56
216.	Pandex	56
217.	Panhematin	56
218.	Panheprin	56
219.	Panmist	56
220.	Penbritin-S	56
221.	Pentane	56
222.	Pentaspán	56
223.	Phanasin	56
224.	Podactin	56
225.	Prandin	56
226.	Sandrena	56
227.	Talacen	56
228.	Taladine	56
229.	Tanafed Dp	56
230.	Tannic Acid	56
231.	Taxadone	56
232.	Teebacin	56
233.	Terazoosin	56
234.	Tetracon	56
235.	Tolmetin	56
236.	Travatan	56
237.	Tricetin	56
238.	Tridecane	56
239.	Uni-Tann D	56

No.	Name	POCA Score (%)
240.	Valbazen	56
241.	Varithena	56
242.	(b) (4) ***	56
243.	Zamicet	56
244.	Zileuton	56
245.	Zimovane	56
246.	Zinbryta (b) (4) ***	56
247.	Zinc, Chelated	56
248.	Zinimin	56
249.	Zinotic Es	56
250.	Aconitate	55
251.	Ambien	55
252.	Anectine	55
253.	Antacid M	55
254.	Antagon	55
255.	Benztroine	55
256.	Betadine	55
257.	Bosentan	55
258.	Canrenone	55
259.	Fenbufen	55
260.	Fenesin	55
261.	Gabapentin	55
262.	Genamin	55
263.	Granisetron	55
264.	Indocin	55
265.	Jeridin	55
266.	Ladropen	55
267.	Memantine	55
268.	Naringenin	55
269.	Netupitant	55
270.	Nydrane	55
271.	Panshape M	55

No.	Name	POCA Score (%)
272.	Phenazine	55
273.	Phenazine 50	55
274.	Phenazine-35	55
275.	Phimetin	55
276.	Sanafitil	55
277.	Sani-Clens	55
278.	Somnicin	55
279.	Sonazine	55
280.	Staphlipen	55
281.	Talzenna	55
282.	Tamofen	55
283.	Tanderil	55
284.	Tegison	55
285.	Tin-Ben	55
286.	Tranxene	55
287.	Vendone	55
288.	Viceton	55
289.	Xalatan	55
290.	Zotepine	55
291.	Zydaclin	55
292.	Zymine D	55

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/s/

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04/26/2024 09:42:25 AM

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04/26/2024 10:50:02 AM

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04/26/2024 06:55:10 PM