

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205555Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)  
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\*\*\***

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<b>Date of This Review:</b>	November 1, 2016
<b>Application Type and Number:</b>	NDA 205555
<b>Product Name and Strength:</b>	Steritalc (talc) powder, 2 gram, 3 gram, and 4 gram
<b>Product Type:</b>	Single ingredient product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Novatech S.A.
<b>Panorama #:</b>	2016-10181737
<b>DMEPA Primary Reviewer:</b>	Tingting Gao, PharmD
<b>DMEPA Team Leader:</b>	Chi-Ming (Alice) Tu, PharmD

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Steritalc, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the August 19, 2016 proprietary name submission.

- Intended Pronunciation: [steritalc]
- Active Ingredient: talc
- Indication of Use: (b) (4) malignant pleural effusion and pneumothorax
- Route of Administration: intrapleural
- Dosage Form: powder
- Strength: 2 gram, 3 gram, and 4 gram
- Dose and Frequency:
  - Malignant Pleural Effusion: intrapleural 2 g to 5 g once.
  - Pneumothorax: intrapleural (b) (4) 2 g once.
- How Supplied:
  - Two grams of talc in a single use 50 mL (b) (4) vial (Type III) and closed by a (b) (4) stopper and crimped with an aluminum cap; (b) (4) (b) (4) 4 vials are packaged in one carton.
  - Four grams of talc in a single use 50 mL (b) (4) vial (Type III) and closed by a (b) (4) stopper and crimped with an aluminum cap; (b) (4) (b) (4) 4 vials are packaged in one carton.
  - Three grams of talc in a 10 mL brown glass (Type I) vial, closed by a (b) (4) stopper and crimped with an aluminum cap; (b) (4) (b) (4) containing (b) (4) vials are packaged in one carton.
- Storage: Store the powder at 20-25°C (68-77°F); excursions permitted between 15°C to 30°C (59°F - 86°F) [see USP Controlled Room Temperature]. Protect against sunlight.
- Container and Closure Systems:
  - For 2 gram and 4 gram: 50 mL (b) (4) vial (Type III) and closed by a (b) (4) stopper and crimped with an aluminum cap
  - For 3 gram: 10 mL brown glass (Type I) vial, closed by a (b) (4) stopper and crimped with an aluminum cap
- Listed Drug: Sterile Talc Powder (NDA 021388) and Sclerosol (NDA 020587)

## **2 RESULTS**

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

### **2.1 MISBRANDING ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

### **2.2 SAFETY ASSESSMENT**

The following aspects were considered in the safety evaluation of the name.

#### ***2.2.1 United States Adopted Names (USAN) Search***

There is no USAN stem present in the proprietary name<sup>a</sup>.

#### ***2.2.2 Components of the Proposed Proprietary Name***

The Applicant did not provide a derivation or intended meaning for the proposed name, Steritalc 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 are misleading or can contribute to medication error. We note that the proposed proprietary name, Steritalc, contains the established name, talc. Since the active ingredient of this product is talc, we did not find the inclusion of established name in the proprietary name misleading or can contribute to a medication error.

#### ***2.2.3 FDA Name Simulation Studies***

Ninety-seven practitioners participated in DMEPA's prescription studies. One response, "Sterile Talc", in the outpatient written prescription study overlapped with a currently marketed product, Sterile Talc Powder. We evaluated this further and noted that both products contain the same active ingredient, talc, are indicated for malignant pleural effusion, have the same route of administration (intrapleural), and share an overlapping dose of 5 gram. Therefore, confusion between these two products will result in minimal clinical consequences (see Appendix E).

The remaining responses did not sound or look similar to any currently marketed products or any products in the pipeline. In the written studies, 58 of 67 participants correctly interpreted the proposed name as "Steritalc". In the voice study, 21 of 30 participants correctly interpreted the proposed name as "Steritalc". Appendix B contains the results from the verbal and written prescription studies.

#### ***2.2.4 Comments from Other Review Disciplines at Initial Review***

In response to the OSE, September 21, 2016 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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<sup>a</sup> USAN stem search conducted on September 28, 2016.

### 2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of  $\geq 55\%$  retrieved from our POCA search<sup>b</sup> organized as highly similar, moderately similar or low similarity for further evaluation.

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	10
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	308
Low similarity name pair: combined match percentage score $\leq 54\%$	0

### 2.2.6 *Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities*

Our analysis of the 318 names contained in Table 1 determined 318 names will not pose a risk for confusion as described in Appendices C through H.

### 2.2.7 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on October 21, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on November 1, 2016, they stated no additional concerns with the proposed proprietary name, Steritalc.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 19, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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<sup>b</sup> POCA search conducted on September 28, 2016 in version 4.0.

## 4 REFERENCES

1. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

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](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.

### 3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

## 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. <sup>c</sup>

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<sup>c</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

**\*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.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there medical and/or coined abbreviations in the proprietary name?</b>
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	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)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	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)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	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, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 54\%$ .

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
  - Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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.
- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

- 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i> ), is there a different number or placement of upstroke/downstroke letters present in the names?	<b>Y/N</b>	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?
<b>Y/N</b>	Do the infixes of the name appear dissimilar when scripted?		
<b>Y/N</b>	Do the suffixes of the names appear dissimilar when scripted?		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).**

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b>with</b> overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 54\%$ ).**

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Steritalc Study (Conducted on September 30, 2016)**

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <p><i>Steritalc, administer 3 g intrapleurally once</i></p>	<p>Steritalc two gram</p> <p>Bring to clinic</p>
<p>Outpatient Prescription:</p> <p><i>Steritalc 2 g</i></p> <p><i>Bring to clinic</i></p> <p><i># 1 vial</i></p>	<p>Dispense one vial</p>

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Study Name: Steritalc**

As of Date 10/21/2016

309 People Received Study

97 People Responded

Total	29	30	38	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DAIRY TALC	0	1	0	1
STARITALC	1	0	0	1
STERI TALC	0	3	0	3
STERILE TALC	1	0	0	1
STERITALC	22	21	36	79
STERI-TALC	0	2	0	2
STERI-TALC 2GM	0	1	0	1
STERITALE	5	0	2	7
STERITALK	0	1	0	1
STERITALP	0	1	0	1

**Appendix C:** Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ )

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally once	<b>POCA Score (%)</b>	<b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b>  <b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b>
1.	Citrical	70	This is an international product formerly marketed in United Kingdom.
2.	Ostercal-D	75	<p><b>Orthographic difference:</b> Ostercal-D begins with the letter string “Os” which appears orthographically different than the letter “S” in Steritalc. Additionally, Steritalc has a letter “c” at the 9<sup>th</sup> position after the letter “l”, which appears orthographically different than the letter “-D” at the 9<sup>th</sup> position for Ostercal-D.</p> <p><b>Phonetic difference:</b> The first syllable in the name Ostercal-D begins with “Os” which sounds distinct from the “Ste” in Steritalc.</p>
3.	Special C	70	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Spiretic	70	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Star-Otic	72	<p><b>Orthographic difference:</b> Star-Otic ends with the letter string “Otic” which appears orthographically different than the letter string “talc” in Steritalc.</p> <p><b>Phonetic difference:</b> The last syllable “Otic” in Star-Otic sounds distinct from the last syllable in Steritalc.</p> <p><b>Other prevention of failure mode:</b> Star-Otic (glycerin/isopropyl alcohol) is discontinued.</p>
6.	Steribath	70	This is an international product formerly marketed in United Kingdom.

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b>  <b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b>
7.	Steri-Stat	79	<b>Orthographic difference:</b> Steri-Stat ends with the letter string “Stat” which appears orthographically different than the letter string “talc” in Steritalc.  <b>Phonetic difference:</b> The third syllable “Stat” in Steri-Stat sounds distinct from the third syllable “talc” in Steritalc.  <b>Other prevention of failure mode:</b> Steri-Stat (Chlorhexidine Gluconate 4%) is discontinued.
8.	Steritalc***	100	This name is the subject of this review.
9.	Trital SR	70	<b>Orthographic difference:</b> Trital SR begins with the letter “T” which appears orthographically different than the letter “S” in Steritalc. Additionally, Steritalc has 9 letters, whereas the root name of Trital SR only has 6 letters.  <b>Phonetic difference:</b> The first syllable “Tri” and second syllable “tal” in the name Trital SR sounds distinct from the first syllable “Ste” and second syllable “ri” in Steritalc. Additionally, Trital SR contains extra syllables from the modifier “SR”.  <b>Other prevention of failure mode:</b> Trital SR (acetaminophen/chlorpheniramine mal/ phenylephrine hcl/phenyltoloxamine) is discontinued and there are no generic products available.
10.	Veteribac	70	Veterinary product. This is a topical antiseptic cleansing solution used for cleaning of wounds, skin lacerations, cuts, abrasions, skin irritations, post-surgical incision sites, burns and hot spots in animal species.

**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.	Actedril	56
2.	After Bite	60
3.	After Bite Plus	58
4.	Afterpill	64
5.	(b) (4)	68
6.	Berinert	55
7.	Brevital***	56
8.	(b) (4)	58
9.	Citracal + D	68
10.	(b) (4)	64
11.	Farbital	61
12.	Noritate	55
13.	Oyster Cal	68
14.	Oyster Cal 500	68
15.	Oyster Calcium	57
16.	Oyster Shell	56
17.	Oyster Shell/D	56
18.	Oystercal D	68
19.	Perisol	56
20.	Sacubitril	56
21.	Satogesic	58
22.	Satric	59
23.	Sectral	58
24.	Serathide	55
25.	Sertraline	60
26.	Sipuleucel-T	58
27.	Sorbitol	58
28.	Spearmint Oil	56
29.	Spectracef	57
30.	Spherosol	56
31.	Sprintec	66
32.	Spritam	61
33.	Stagesic	66
34.	Stagesic-10	66
35.	Star Anise Oil	56
36.	Starlix	60
37.	Stay Alert	60
38.	Stelara	56
39.	Sterile Water	58
40.	Steril-Eyes	62
41.	Sterilube	65

No.	Name	POCA Score (%)
42.	Steroform	60
43.	Stevioside	57
44.	Stie-Cort	66
45.	Stribild	69
46.	Striverdi***	61
47.	Sureclick***	58
48.	Terbutaline	56
49.	Teril	56
50.	Titralac	65
51.	Trace Metal	55
52.	Trental	60
53.	Triacet	58
54.	Tricosal	58
55.	Triferic	60
56.	Trileptal	61
57.	Tri-Nasal	57

**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: Steritalc Established name: Talc Dosage form: Powder Strength(s): 2g, 3g, and 4g Usual Dose: 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	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.	Esoterica	66	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different. Esoterica contains two extra syllables.
2.	Estra-C	59	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.
3.	Estrace	56	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
4.	Histex AC	55	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Histex AC contains an extra syllable from the modifier “AC”.</p>
5.	Histex SR Tablet	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Histex SR Tablet contains extra syllables from the modifier “SR Tablet”.</p>
6.	Kristalose	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
7.	Lacrisert	62	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
8.	Meperitab	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
9.	Peri-Colace	57	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
10.	Periostat	59	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
11.	Portalac	64	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
12.	Restoril	57	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
13.	Sarisol	57	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
14.	Sarisol No. 1	55	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Sarisol No. 1 contains extra syllables from the modifier “No. 1”.</p>
15.	Sarisol No. 2	55	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Sarisol No. 2 contains extra syllables from the modifier “No. 2”.</p>
16.	Scalacort	63	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
17.	Sclerosol	59	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
18.	Scrub-Stat	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
19.	Scrub-Stat 2***	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Scrub-Stat 2*** contains an extra syllable from the modifier “4”.</p>
20.	Scrub-Stat 4***	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Scrub-Stat 4*** contains an extra syllable from the modifier “4”.</p>
21.	Secobarbital	61	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Secobarbital contains extra syllables.</p>
22.	Secretin	57	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
23.	Serostim LQ	62	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Serostim LQ contains extra syllables from the modifier “LQ”.</p>
24.	Silver Citrate	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Silver Citrate contains an extra syllable.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
25.	Sorbitrate	56	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.
26.	Soriatane	57	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.
27.	Sotradecol	56	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different. Sotradecol contains an extra syllable.
28.	Sprycel	56	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.
29.	Stelazine	56	The infix and suffix of this name pair have sufficient orthographic differences.  The second and third syllables of this name pair sound different.
30.	Sterane	58	The suffix of this name pair has sufficient orthographic differences.  The second syllables of this name pair sound different. Steritalc contains an extra syllable.
31.	Sterapred	64	The suffix of this name pair has sufficient orthographic differences.  The third syllables of this name pair sound different.

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
32.	Sterapred DS	61	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different. Sterapred DS contains extra syllables from the modifier “DS”.</p>
33.	Sterile Talc Powder	56	<p>Both products contain the same active ingredient, talc, are indicated for malignant pleural effusions, have the same route of administration (intrapleural), and share an overlapping dose of 5 gram. Therefore, confusion between these two products will result in minimal clinical consequences.</p>
34.	Strattera	62	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
35.	Strensiq	60	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
36.	Striant	61	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
37.	Stridex	61	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
38.	Stri-Dex	61	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
39.	<sup>(b) (4)</sup>	56	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
40.	Stromectol	56	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
41.	<sup>(b) (4)</sup>	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
42.	Tera Gel	60	<p>The prefix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, and third syllables of this name pair sound different.</p>
43.	Terazol 3	58	<p>The prefix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, and third syllables of this name pair sound different. Terazol 3 contains an extra syllable from the modifier “3”.</p>
44.	Terazol 7	58	<p>The prefix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, and third syllables of this name pair sound different. Terazol 7 contains an extra syllable from the modifier “7”.</p>
45.	<sup>(b) (4)</sup>	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b) (4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
46.	Tetravisc	64	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
47.	Thera-Sal	64	<p>The prefix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, and third syllables of this name pair sound different.</p>
48.	Tricalm	64	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Steritalc contains an extra syllable.</p>
49.	Tricitrates	56	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Tricitrates contains an extra syllable.</p>
50.	Vaseretic	68	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Vaseretic contains an extra syllable.</p>
51.	Vaseretic 10-25	68	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Vaseretic 10-25 contains extra syllables from the modifier “10-25”.</p>
52.	Vaseretic 5-12.5	68	<p>The prefix, infix, and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Vaseretic 5-12.5 contains extra syllables from the modifier “5-12.5”.</p>

No.	<b>Proposed name:</b> Steritalc <b>Established name:</b> Talc <b>Dosage form:</b> Powder <b>Strength(s):</b> 2g, 3g, and 4g <b>Usual Dose:</b> 2 g to 5 g intrapleurally <sup>(b)(4)</sup>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
53.	Vistaril	58	The prefix, infix, and suffix of this name pair have sufficient orthographic differences.  The first, second, and third syllables of this name pair sound different.

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 54\%$ )

No.	Name	POCA Score (%)
1.	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
1.	Astri-Uc	59	Veterinary product.
2.	Barbital	59	The product is discontinued and there are no generics available.
3.	Baseretic	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Betaloc	56	International product marketed in several foreign countries not including the USA.
5.	Calteridol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Citral	56	Product is not a drug. It is an aroma compound used in perfumery for its citrus effect. It is also used as a flavor and for fortifying lemon oil.
7.	Crystal B-12	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Dritail	58	Veterinary product.
9.	Estracyt	63	International product marketed in several foreign countries not including the USA.
10.	Estrate La	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Estriol	60	Veterinary product.
12.	Fam-Pericols	57	This product is discontinued in the United States with no generics available.
13.	Meritate	60	This product is discontinued and there are no generics available.
14.	Metharbital	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Satraplatin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Scalp-Cort	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Scarlet Red	57	Veterinary product.
18.	Schering PC4	58	International product formerly marketed in United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
19.	Sclero Seal	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Scleromate	57	This is an unapproved drug product that has been discontinued, and there are no generics available.
21.	Sea Salt	60	Product is not a drug. It is a salt produced from the evaporation of seawater, and is used in cooking and cosmetics.
22.	Semitard MC	56	International product formerly marketed in United Kingdom
23.	(b) (4)	62	(b) (4)
24.	Serenace	57	International product marketed in in Australia, Japan, New Zealand, Ireland, Hong Kong, Indonesia, Philippines, South Africa, Singapore, and India.
25.	Serentil	64	NDA 016774, NDA 016775, and NDA 016997 are Withdrawn Pending FR Notice as of 09/09/2008. No generic equivalents available.
26.	Sericin 1	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Serpalan	58	This product (Reserpine tablets) is no longer available in the United States.
28.	Serpasil	60	NDA 009115 and NDA 009434 are Withdrawn FR Effective 8/5/1996. No generic equivalents available.
29.	Serpate	56	NDA 009453 is Withdrawn FR Effective 3/20/1992. No generic equivalents available.
30.	Serpivite	56	NDA 009645 is Withdrawn FR Effective 4/1/1994. No generic equivalents available.
31.	Serutan	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Skilcraft	58	Product is not a drug. It is an anti-bacterial wipe cloth used for hand washing.
33.	Spectramast	55	Veterinary product.
34.	Spermaceti	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
35.	Spirapril	62	This is the established name of an international product currently marketed in Italy.
36.	Spiroctan	58	International product marketed in Brazil and France
37.	Starch, Rice	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Starflex	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Staycept	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Stearamide	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Stearamine	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
42.	Stearate	61	This is an inactive ingredient (e.g., aluminum stearate, magnesium stearate, erythromycin stearate).
43.	Steareth-10	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	Steareth-100	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Steareth-12	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	Steareth-15	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Steareth-2	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
48.	Steareth-20	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Steareth-21	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
50.	Steareth-22	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Steareth-3	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
52.	Steareth-30	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	Steareth-4	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
54.	Steareth-7	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	Stearic Acid D7	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	Stearyl Alcohol	55	Product is not a drug. It is an ingredient used in skin care products.
57.	(b) (4)	58	This is a secondary proposed name; NDA 22210 was approved as Zenpep.
58.	Stemetil	65	International product marketed in United Kingdom, Canada, and Australia.
59.	Stemetil Eff	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Sterile Urea	58	NDA 017698 is Withdrawn FR Effective 11/12/2015. No generic equivalents available.
61.	Sterillium	61	International product marketed in Sweden, Germany, Ireland, Greece and France
62.	Steripod Pink	55	Product is not a drug. It is a toothbrush sanitizer.
63.	(b) (4)	64	Proposed name withdrew by Applicant for NDA 022305. NDA 022305 approved and marketed under the proprietary name, Pur-Wash.
64.	Sterogyl	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	Ster-Zac-Bath	58	International product marketed in United Kingdom.
66.	Stesolid	56	International product marketed in Denmark, United Kingdom, Germany, Norway, Hungary, Israel, Thailand, Austria, and Portugal.

No.	Name	POCA Score (%)	Failure preventions
67.	Steviol	58	Product is not a drug. It occurs in the plant as steviol glycosides, which is sweet compounds used as sugar substitutes.
68.	Stiedex Lp	55	International product marketed in United Kingdom.
69.	Stilbestrol	56	NDA 004056 is Withdrawn FR Effective 9/13/2000. No generic equivalents available.
70.	Stilbetin	56	NDA 004056 is Withdrawn FR Effective 9/13/2000. No generic equivalents available.
71.	Stilnoct	56	International product marketed in Denmark, Finland, Ireland, Netherlands, Norway, Sweden, Belgium, and United Kingdom.
72.	Strawberry C	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Streptase	64	Product is discontinued in the United States in December 2014, and is currently marketed in Chile.
74.	Strix	56	The product is discontinued and there are no generics available.
75.	Styramate	61	International name formerly marketed in South Africa.
76.	Suprefact	57	International product marketed in Canada, Europe, Asia, Mexico, and South Africa
77.	Surital	69	NDA 007600 is Withdrawn Pending FR Notice as of 9/17/2001. No generic equivalents available.
78.	Tearisol	64	Product is discontinued and there are no generic equivalents available.
79.	Terfinax	56	This product contained terfenadine and was discontinued for safety reasons.
80.	Teril Cr	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
81.	Teronac	59	International product marketed in Hungary, Ireland, Israel, Netherland, Switzerland, United Kingdom, Germany, South Africa, Indonesia, Greece
82.	Terrasil	66	International product formerly marketed in Thailand.
83.	Tertatolol	56	This is the established name of an international product currently marketed in France, Portugal, and Singapore.
84.	Tetrasilane	56	Product is not a drug. It is a chemical compound.
85.	Triperidol	58	International product marketed in United Kingdom, Germany, Belgium, France, India

No.	Name	POCA Score (%)	Failure preventions
86.	Tritec	63	NDA 020559 is Withdrawn FR Effective 9/13/2000. No generic equivalents available.
87.	Tumeric Oil	56	Product is not a drug. It is a homeopathic product.
88.	Zycortal	56	Veterinary product.

**Appendix H:** Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Acetasol Hc	56
2.	Aspartame	55
3.	Aspartate	62
4.	Aspirtab	57
5.	Bile Salts	56
6.	Cardiotec	55
7.	Carticel	57
8.	Castor Oil	57
9.	(b) (4)	58
10.	Cerasport	56
11.	Ceretec	62
12.	(b) (4)	55
13.	(b) (4)	56
14.	Cervidil	55
15.	Cetiedil	57
16.	Cetraxal	62
17.	Cheracol D	56
18.	Citracal	65
19.	Citric Acid	60
20.	Citrucel	59
21.	Citrucel Sf	58
22.	Clearasil	56
23.	(b) (4)	56
24.	Edarbi Clt***	58
25.	Efcortelan	56
26.	(b) (4)	56
27.	Estra Aq	55
28.	Estraderm	56
29.	Estradiol	62
30.	Estrasorb	57
31.	Estratab	62
32.	Estratest	64

No.	Name	POCA Score (%)
33.	Estrogel	56
34.	Estroplan	56
35.	Estro-Span C	58
36.	Estrumate	55
37.	Fer-In-Sol Tr	56
38.	Ferriseltz	64
39.	Ferlecit	56
40.	Florical	56
41.	Fortical	56
42.	Gastrese-La	56
43.	(b) (4)	58
44.	Hydrisalic	58
45.	Ismo Retard	58
46.	Isoket Retard	56
47.	Isotrater Er	56
48.	Keralac	56
49.	Kerasal	56
50.	Keratol	56
51.	Keratol 40	56
52.	Keratol Hc	66
53.	Keratolux	55
54.	(b) (4)	60
55.	Mestranol	57
56.	Permitil	60
57.	Prialt	56
58.	Psoriatec	66
59.	Psorigel	56
60.	Risperdal	61
61.	Tegretol	59
62.	Tegretol Xr	56
63.	Tegretol-Xr	56
64.	Temaril-P	57
65.	Tenoretic	62
66.	Tenoretic 100	62
67.	Tenoretic 50	62
68.	Testradiol	57
69.	Tetracap	60
70.	Tetrachel	62
71.	Tetralysal	58
72.	Thera Tears	59
73.	Theracort	61
74.	Theracys	57
75.	Thera-Gesic	56

<b>No.</b>	<b>Name</b>	<b>POCA Score (%)</b>
76.	Therahist	56
77.	Therastat	60
78.	Theratears	59
79.	Therevac	59
80.	Thimerosal	60
81.	Ticarcillin	55
82.	Tiger Balm	56
83.	Tipiracil	62
84.	Tolrestat	56
85.	Torisel	60
86.	Totaretic	66
87.	Tranilast	56
88.	Triac Cold	60
89.	Triacin C	57
90.	Triacin-C	57
91.	Triacort	58
92.	Triclos	56
93.	Tri-Dec	56
94.	Trifed C	56
95.	Trilisate	58
96.	Trimal Dh	56
97.	Trinalin	57
98.	Trintellix	58
99.	Triostat	56
100.	Tri-Otic	57
101.	Tri-Pase	56
102.	Tri-Tannate	55
103.	Ultrasal	56
104.	Veracolate	55
105.	Verticalm	62
106.	Vetrimec	55
107.	Vitrasert	62
108.	Westrim La	55
109.	Xerac Ac	55
110.	Zestoretic	63

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/s/  
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TINGTING N GAO  
11/01/2016

CHI-MING TU  
11/01/2016