

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208313Orig1s000**

**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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**Date of This Review:** May 11, 2018

**Application Type and Number:** NDA 208313

**Product Name and Strength:** Infugem (gemcitabine in 0.9% sodium chloride injection), 10 mg/mL

**Total Product Strength:** 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL, 2,200 mg in 220 mL

**Product Type:** Single Ingredient Product

**Rx or OTC:** Rx

**Applicant/Sponsor Name:** Sun Pharmaceutical Industries, Ltd.

**Panorama #:** 2018- 21113657

**DMEPA Safety Evaluator:** Janine Stewart, PharmD

**DMEPA Team Leader:** Chi-Ming (Alice) Tu, PharmD, BCPS

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Infugem, 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 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Infugem on November 23, 2016 with amendments submitted on December 7, 2016 and December 9, 2016 to clarify the proposed proprietary name to be reviewed. We found the name acceptable under NDA 208313 on February 13, 2017.<sup>a</sup> However, the Application received a Complete Response (CR) on May 23, 2017.

Thus, in this Class 2 Resubmission, the Applicant submitted the name, Infugem, for reevaluation on February 16, 2018. There is no change in product characteristics for this proposed product.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 16, 2018.

Intended Pronunciation	in-fu-gem
Active Ingredient	Gemcitabine in 0.9% sodium chloride injection
Indication of Use	<ol style="list-style-type: none"><li>1. In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.</li><li>2. In combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.</li><li>3. In combination with cisplatin for the treatment of non-small cell lung cancer.</li><li>4. As a single agent for the treatment of pancreatic cancer.</li></ol>
Route of Administration	Intravenous
Dosage Form	Injection (Ready to administer intravenous infusion)
Strength	1,200 mg/120 mL, 1,300 mg/130 mL, 1,400 mg/140 mL, 1,500 mg/150 mL, 1,600 mg/160 mL, 1,700 mg/170 mL,

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<sup>a</sup> Townsend.O. Proprietary Name Review for Infugem (gemcitabine). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 FEB 13. Panorama No. 2016-11588186.

	1,800 mg/180 mL, 1,900 mg/190 mL, 2,000 mg/200 mL, 2,200 mg/220 mL (10 mg/mL)
Dose and Frequency	<p>Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p> <p>Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p> <p>Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p> <p>Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</p>
How Supplied	<p>1 single (b) (4) bag per carton:</p> <p>1,200 mg in 120 mL</p> <p>1,300 mg in 130 mL</p> <p>1,400 mg in 140 mL</p> <p>1,500 mg in 150 mL</p> <p>1,600 mg in 160 mL</p> <p>1,700 mg in 170 mL</p> <p>1,800 mg in 180 mL</p> <p>1,900 mg in 190 mL</p> <p>2,000 mg in 200 mL</p> <p>2,200 mg in 220 mL</p>
Storage	Store at 25°C (77°F) (b) (4) excursions between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature]
Container and Closure Systems	(b) (4)
Reference Listed Drug	Gemzar (gemcitabine) For Injection, NDA 020509

## 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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 2 (DOP2) 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>b</sup>.

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

The Applicant indicated in their submission that the proposed name, Infugem, is derived from the phrase, "gemcitabine infusion". This proprietary name is comprised of a single word that does not contain a modifier, route of administration, dosage form, or any components that are misleading or can contribute to medication error.

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

In response to the OSE, March 1, 2018 e-mail, the Division of Oncology Products 2 (DOP2) stated:

"I agree that the proprietary name is not misleading, but I can't help but notice the resemblance of "Infugem" to the word "infusion" – depending on how it's pronounced. I'm not certain I can conceive of a specific situation in which this might lead to a safety issue, but since the word "infusion" is used frequently in infusion centers and the supplying pharmacies, there seems to me to be at least a potential for confounding the two. I just thought I'd mention it, and will defer to DMEPA."

We agree that the proposed proprietary name, Infugem, may evoke the word "infusion". While FDA generally recommends that sponsors avoid incorporating product-specific attributes, such as route of administration, as part of the proposed proprietary name, including references to product-specific attributes in the root proprietary name may be acceptable if the product-specific attribute is consistent with the terminology used in the product's labeling and does not pose additional risks for medication error. In this case, the product-specific attribute is consistent with the terminology used in the labeling and does not pose additional risks for medication error. Thus, we do not object to the name in this case.

### ***2.2.4 FDA Name Simulation Studies***

Seventy-three practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look like any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

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<sup>b</sup> USAN stem search conducted on March 13, 2018.

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

Our POCA search<sup>c</sup> identified 81 names with a combined phonetic and orthographic score of  $\geq 55\%$  or an individual phonetic or orthographic score  $\geq 70\%$ . We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 4 names not previously analyzed. These names are included in Table 1 below.

### **2.2.6 Names Retrieved for Review Organized by Name Pair Similarity**

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

<b>Table 1. Similarity Category</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	3
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 4 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

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

DMEPA communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on May 4, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP2 on May 11, 2018, they stated no additional concerns with the proposed proprietary name, Infugem.

## **3 CONCLUSION**

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

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<sup>c</sup> POCA search conducted on December 14, 2017 in version 4.2.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your submission, received on February 16, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 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>d</sup>

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<sup>d</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 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 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 54\%$ .

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
  - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names<sup>e</sup>. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
  - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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  $\geq 70\%$ ).**

<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 render the names less likely to confusion, provided that the pair does not share a common strength or dose.</p>			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	<p>Do the names begin with different first letters?</p> <p><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i></p>	<b>Y/N</b>	<p>Do the names have different number of syllables?</p>
<b>Y/N</b>	<p>Are the lengths of the names dissimilar* when scripted?</p> <p><i>*FDA considers the length of names different if the names differ by two or more letters.</i></p>	<b>Y/N</b>	<p>Do the names have different syllabic stresses?</p>
<b>Y/N</b>	<p>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?</p>	<b>Y/N</b>	<p>Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</p>
<b>Y/N</b>	<p>Is there different number or placement of cross-stroke or dotted letters present in the names?</p>	<b>Y/N</b>	<p>Across a range of dialects, are the names consistently pronounced differently?</p>
<b>Y/N</b>	<p>Do the infixes of the name appear dissimilar when scripted?</p>		
<b>Y/N</b>	<p>Do the suffixes of the names appear dissimilar when scripted?</p>		

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

Step 1	<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>
Step 2	<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><u>with</u></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  $\leq 54\%$ ).**

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. Infugem Study (Conducted on March 19, 2018)**

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <p><i>Infugem 1.25 mg/m<sup>2</sup> IV over 30 minutes</i></p>	<p>Infugem 2,000 mg Bring to clinic</p>
<p>Outpatient Prescription:</p> <div data-bbox="203 640 1112 1186" style="border: 1px solid black; padding: 10px;"> <p>Patient _____ Date _____</p> <p>Address _____</p> <p><b>R</b></p> <p style="text-align: center;"><i>Infugem 2000 mg</i> <i>Bring to infusion clinic</i></p> <p>Refill(s): _____ Dr. <i>OSE</i> _____</p> <p>DEA No. _____ Address _____</p> <p>Telephone _____</p>  </div>	

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

**Study Name: Infugem**

As of Date 4/25/2018

302 People Received Study

73 People Responded

Study Name: Infugem

<b>Total</b>	<b>25</b>	<b>22</b>	<b>26</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
DRIFUGEM	0	0	1	1
ENFUGEM	0	1	0	1
ENFUGEUM	0	1	0	1
ENFUGIM	0	1	0	1
IFUJEM	0	1	0	1
INFAGEM	0	1	0	1
INFLUGEM	0	0	1	1
INFRIGEN	2	0	0	2
INFUEM	0	0	1	1
INFUGEM	19	5	19	43
INFUGEN	4	1	2	7
INFUGIUM	0	2	0	2
INFUGUM	0	3	0	3
INFUJEM	0	1	0	1
INFUJIM	0	1	0	1
INFUJIOM	0	1	0	1
INFUJUM	0	2	0	2
INGUGEM	0	1	0	1
POFUGEON	0	0	1	1
PUFUGEM	0	0	1	1

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

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL, 2,200 in 220 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b></p> <p><b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b></p>
n/a			

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

No.	Name	POCA Score (%)
n/a		

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

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL, 2,200 in 220 mL (10 mg/mL)</p> <p><b>Usual Dose:</b>  <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul> </p>	POCA Score (%)	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	Invokana	52	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
2.	Endodan	50

**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
3.	Anthisan	52	International product.
4.	Multifuge	54	Name identified in Drugs@FDA database. This product is discontinued with no generic equivalent available for human use. The generic piperazine citrate is available as a veterinary product.

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion<sup>f</sup>.

No.	Name	POCA Score (%)
	N/A	

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<sup>f</sup> Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JANINE A STEWART  
05/11/2018

CHI-MING TU  
05/11/2018

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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>	February 13, 2017
<b>Application Type and Number:</b>	NDA 208313
<b>Product Name and Strength:</b>	Infugem (gemcitabine hydrochloride in sodium chloride injection), 10 mg/mL
<b>Total Product Strength:</b>	1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Sun Pharmaceutical Industries, Ltd.
<b>Panorama #:</b>	2016-11588186
<b>DMEPA Primary Reviewer:</b>	Otto L. Townsend, PharmD
<b>DMEPA Team Leader:</b>	Chi-Ming (Alice) Tu, PharmD, BCPS

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Infugem, 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 submitted an external name study conducted by the (b) (4) for this product.

### 1.1 REGULATORY HISTORY

The Applicant submitted the name, Infugem, for review on November 23, 2016 with amendments being submitted on December 7, 2016 and December 9, 2016 to clarify the proposed proprietary name to be reviewed.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the November 23, 2016 proprietary name submission.

Intended Pronunciation	in-fu-gem
Active Ingredient	Gemcitabine hydrochloride
Indication of Use	<ol style="list-style-type: none"><li>1. In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.</li><li>2. In combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.</li><li>3. In combination with cisplatin for the treatment of non-small cell lung cancer.</li><li>4. As a single agent for the treatment of pancreatic cancer.</li></ol>
Route of Administration	Intravenous
Dosage Form	Injection (Ready-to-Infuse Bag)
Strength	1,200 mg/120 mL, 1,300 mg/130 mL, 1,400 mg/140 mL, 1,500 mg/150 mL, 1,600 mg/160 mL, 1,700 mg/170 mL, 1,800 mg/180 mL, 1,900 mg/190 mL, 2,000 mg/200 mL (10 mg/mL)
Dose and Frequency	<p>Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p> <p>Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p> <p>Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</p>

	Pancreatic Cancer: 1,000 mg/m <sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.
How Supplied	1,200 mg in 120 mL 1,300 mg in 130 mL 1,400 mg in 140 mL 1,500 mg in 150 mL 1,600 mg in 160 mL 1,700 mg in 170 mL 1,800 mg in 180 mL 1,900 mg in 190 mL 2,000 mg in 200 mL
Storage	Store at 25°C (77°F) [redacted] (b) (4) excursions between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature]
Container and Closure Systems	[redacted] (b) (4)

## 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 concurred and the Division of Oncology Products 2 (DOP2) aligned with the findings of OPDP's assessment of the proposed name (See section 2.2.4 below).

### 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>.

<sup>a</sup> USAN stem search conducted on December 29, 2016.

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

The Applicant indicated in their submission that the proposed name, Infugem, is derived from the phrase, “gemcitabine infusion”. This proprietary name is comprised of a single word that does not contain a modifier, route of administration, dosage form, or any components that are misleading or can contribute to medication error.

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

Eighty-one practitioners participated in DMEPA’s prescription studies. 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. Common misinterpretations includes misinterpreting the last letter “m” in Infugem as “n” (n=16) in outpatient and inpatient written studies. 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, December 28, 2016 e-mail, DOP2 stated,

The proposed name “Infugem” is probably a condensation of “Infusible Gemcitabine” referring to its liquid RTU composition, rather than lyophilized LD form that requires reconstitution.

My only concern is that there are, and may be future, additional liquid Gemcitabines (Accord/Intas NDA 209604 is an example), and this name might be seen as implying a “unique” property or suggesting superiority of the drug product.

We shared concerns expressed by DOP2 with OPDP. OPDP replied on January 30, 2017 and stated,

OPDP has considered the comments from DOP2 regarding the proposed proprietary name Infugem. However, we continue to maintain our non-objection to the proposed trade name Infugem from a promotional perspective. Given the fact that the product is an injectable formulation of gemcitabine hydrochloride intended for intravenous administration (supplied in infusion bags), the trade name as proposed would not be false or misleading if approved. Therefore, we do not believe that the name poses a significant promotional concern.

Based on the input provided by OPDP and past input from the FDA Office of the Chief Counsel (OCC) regarding objecting to a proposed proprietary name based on promotional, misleading or misbranding aspects, DMEPA agreed with OPDP’s determination that we lack the basis to find this name unacceptable for misbranding reasons. We informed DOP2 of our misbranding evaluation via email on February 2, 2017, and offered to meet with DOP2 if further discussion is warranted. DOP2 aligned with our misbranding evaluation and did not request to meet.

### **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> and also includes names identified from the FDA Prescription

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<sup>b</sup> POCA search conducted on December 29, 2016 in version 4.0.

Simulation Study and (b) (4). These names are organized as highly similar, moderately similar or low similarity for further evaluation.

<b>Table 1. Similarity Category</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	83
Low similarity name pair: combined match percentage score $\leq 54\%$	8

### ***2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength***

The proposed product, Infugem will be available in the following strengths: 1,200 mg, 1,300mg, 1,400 mg, 1,600 mg, 1,700 mg, 1,800 mg, 1,900 mg, and 2,200 mg. Since these are not typical strengths that are commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Infugem that were not identified in POCA. Our eDRLS search did not identify any additional names of concern.

<b>Table 1A. eDRLS Search Results<sup>c</sup></b>	<b>POCA Score (%)</b>
N/A	

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

Our analysis of the 93 names contained in Table 1 determined none of the names would pose a risk for confusion as described in Appendices C through H.

### ***2.2.8 Communication of DMEPA’s Analysis at Midpoint of Review***

DMEPA communicated our findings to DOP2 via e-mail on February 7, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP2 on February 9, 2017, they stated no additional concerns with the proposed proprietary name, Infugem.

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<sup>c</sup> eDRLS search conducted on December 29, 2016.

### **3 CONCLUSIONS**

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

#### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your November 23, 2016 submission, December 7, 2016 and December 9, 2016 amendments are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 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>d</sup>

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<sup>d</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  $\geq 70\%$ ).**

<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 render the names less likely to confusion, provided that the pair does not share a common strength or dose.</p>			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	<p>Do the names begin with different first letters?</p> <p><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i></p>	<b>Y/N</b>	<p>Do the names have different number of syllables?</p>
<b>Y/N</b>	<p>Are the lengths of the names dissimilar* when scripted?</p> <p><i>*FDA considers the length of names different if the names differ by two or more letters.</i></p>	<b>Y/N</b>	<p>Do the names have different syllabic stresses?</p>
<b>Y/N</b>	<p>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?</p>	<b>Y/N</b>	<p>Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</p>
<b>Y/N</b>	<p>Is there different number or placement of cross-stroke or dotted letters present in the names?</p>	<b>Y/N</b>	<p>Across a range of dialects, are the names consistently pronounced differently?</p>
<b>Y/N</b>	<p>Do the infixes of the name appear dissimilar when scripted?</p>		
<b>Y/N</b>	<p>Do the suffixes of the names appear dissimilar when scripted?</p>		

**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><u>with</u></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. Infugem Study (Conducted on January 9, 2017)**

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Infugem 1.250 mg/m<sup>2</sup> IV over 30 minutes</i></p>	<p>Infugem 2,000 mg. Bring to Infusion Center. Dispense #1</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Infugem 2000 mg Bring to Infusion Center</i></p>	

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

**Study Name: Infugem** (As of Date 1/17/2017)

302 People Received Study  
81 People Responded

<b>Total</b>	<b>28</b>	<b>28</b>	<b>25</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
ANFUGEM	0	0	1	1
EMFUGIUM	0	1	0	1
ENFUGEM	0	2	0	2
ENFUGIM	0	2	0	2
ENFUJIM	0	1	0	1
IMFLUGEN	1	0	0	1
INFLUGEM	2	0	1	3
INFLUGEN	2	0	0	2
INFUGEM	14	7	19	40
INFUGEN	9	1	4	14
INFUGIM	0	2	0	2
INFUGIUM	0	2	0	2
INFUGUM	0	2	0	2
INFUGYM	0	1	0	1
INFUJEM	0	1	0	1
INFUJIM	0	2	0	2
INFUJUM	0	1	0	1
INFUJUMP	0	1	0	1
INFUSIM	0	1	0	1
INFUSIN	0	1	0	1

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

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b></p> <p><b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b></p>
1.	Infugem	100	Name is the subject of this review.
2.	Infergen	74	Brand discontinued with no generic available. BLA 103663 revoked effective 03/30/2014; however, not reported in the Federal Register (FR).

**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.	Entsufon	56 (phonetic 70)
2.	Evac-U-Gen	54
3.	Exoderm	50
4.	Imagent	57
5.	Imodium	54
6.	Imogam	56
7.	Indiomin	56
8.	Indium-111	58
9.	Indocin	54 (phonetic 71)

<b>No.</b>	<b>Name</b>	<b>POCA Score (%)</b>
10.	Infasurf	56
11.	Infed	60
12.	Infuvite	69 (orthographic 70)
13.	Innofem	68 (orthographic 75)
14.	Intuniv	60
15.	Isovue-M 200	58
16.	Isovue-M 300	58
17.	Isovue-M-200	58
18.	Isovue-M-300	58
19.	Macugen	60

**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.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	Amphocin	54 (orthographic 76)	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different
2.	Bivigam	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
3.	Epogen	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
4.	Femogen	61	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
5.	Imferon	62	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
6.	Imipenem	66	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different and Imipenem contains an extra syllable.

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
7.	Incivek	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
8.	Infalyte	54	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
9.	Infumorph	60	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
10.	Insulase	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	<p><b>Proposed name:</b> Infugem</p> <p><b>Established name:</b> Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection</p> <p><b>Dosage form:</b> Injection (ready-to-infuse bag)</p> <p><b>Strength(s):</b> 1,200 mg in 120 mL, 1,300 mg in 130 mL, 1,400 mg in 140 mL, 1,500 mg in 150 mL, 1,600 mg in 160 mL, 1,700 mg in 170 mL, 1,800 mg in 180 mL, 1,900 mg in 190 mL, 2,000 mg in 200 mL (10 mg/mL)</p> <p><b>Usual Dose:</b></p> <ul style="list-style-type: none"> <li>•Ovarian Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Breast Cancer: 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Non-Small Cell Lung Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m<sup>2</sup> over 30 minutes on Days 1 and 8 of each 21-day cycle.</li> <li>•Pancreatic Cancer: 1,000 mg/m<sup>2</sup> over 30 minutes once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.</li> </ul>	POCA Score (%)	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
11.	Insulin	64 (orthographic 77)	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
12.	Iveegam	55	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
13.	Neupogen	65 (orthographic 70)	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second 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.	Inulin	54
2.	Invega	54
3.	Invokamet	52
4.	Nucochem	54
5.	Panshape M	48
6.	Phen Tuss DM	52
7.	Senna-Gen	54
8.	Uni Tuss DM	52

**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.	Amtussin	55	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
2.	(b) (4) ***	55	(b) (4)
3.	Ancestim	58	International product marketed in Canada.
4.	Antagon	43	International product formerly marketed in several foreign countries.
5.	Antiben	55	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
6.	Anturane	54	Name identified in the Drugs@FDA database. NDA 011556 is withdrawn federal register effective 6/18/2009, and there are no generic products available.
7.	Centussin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Enduron	50	Brand discontinued with no generic available. NDA 012524 withdrawn FR Effective 04/18/2012.
9.	Femseven 100	62	International product marketed in several foreign countries.

No.	Name	POCA Score (%)	Failure preventions
10.	Femseven 50	62	International product marketed in several foreign countries.
11.	Femseven 75	62	International product marketed in several foreign countries.
12.	Immuzim	60	This is a veterinary product.
13.	Incurin	59	This is a veterinary product.
14.	Indium	58	Product is not a drug. It is a chemical element.
15.	Indobufen	58	International product marketed in several foreign countries.
16.	Infestat	57	International product formerly marketed in the United Kingdom.
17.	(b) (4) **	58	(b) (4)
18.	Inoven	57	International product formerly marketed in the United Kingdom.
19.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2015-1703250). An alternative proposed proprietary name, Logilia*** was submitted and found conditionally acceptable.

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

No.	Name	POCA Score (%)
1.	Amezinium	56
2.	Amsidine	58
3.	Anesgerm	60
4.	Angiozem	62
5.	Empirin	55
6.	Enflurane	59
7.	Fenbufen	61
8.	Fenbuzip	56
9.	Fentazin	56
10.	Feogen	55
11.	Fluogen	56
12.	Fungi-Gone	56
13.	Fungizone	55
14.	Gingi Med	56
15.	Life-O-Gen	58
16.	Lif-O-Gen	64

No.	Name	POCA Score (%)
17.	Menogen	60
18.	Micafungin	56
19.	Mintuss Dm	58
20.	Mintuss Mr	56
21.	Mintuss Ms	56
22.	Monafed Dm	55
23.	Multigen	55
24.	Nefopam	56
25.	Phenflu Dm	62
26.	Phenformin	56
27.	Pimafucin	58
28.	Sinufed	56
29.	Sinumed	56
30.	Sinuvent	56
31.	Tensium	56
32.	Uniferon	58

**Appendix I:** Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Actiq
2.	Azithromycin
3.	Careone Milk of Magnesia
4.	CareOne Mucus Relief ER
5.	DG Health Milk of Magnesia
6.	DG Health Mucus ER
7.	Diflucan
8.	EB301CT Bruise Pain Relief
9.	Equaline Milk of Magnesia
10.	Equaline Mucus ER
11.	Equate Milk of Magnesia
12.	Equate Mucus ER Max
13.	Fentanyl Citrate
14.	Fortical
15.	Good Neighbor Pharmacy Milk Of Magnesia
16.	Good Neighbor Pharmacy Mucus ER
17.	Good Sense Milk Of Magnesia
18.	Guaifenesin Extended Release
19.	HACCP QE2
20.	Harris Teeter Milk of Magnesia
21.	Harris Teeter Mucus Relief Max
22.	Health Mart Mucus D

No.	Name
23.	Healthy Accents Milk of Magnesia
24.	Healthy Accents Mucus Relief
25.	Leader Milk Of Magnesia
26.	Leader Mucus ER Max
27.	Magmex
28.	Medibest Milk of Magnesia
29.	Members Mark mucus relief ER
30.	Milk Of Magnesia
31.	Milk Of Magnesia Cherry
32.	Milk Of Magnesia Mint
33.	Milk Of Magnesia Original
34.	Milk of Magnesia Wild Cherry
35.	Mint Milk of Magnesia
36.	Mucinex
37.	Mucus ER
38.	Mucus ER Max
39.	Mucus Extended Release
40.	Mucus Relief
41.	Mucus Relief ER
42.	Mucus Relief Max
43.	Original - magnesium hydroxide suspension
44.	Phillips Fresh Mint Milk of Magnesia
45.	Phillips Milk Of Magnesia Wild Cherry
46.	Phillips Original Milk Of Magnesia
47.	Provocholine
48.	RiaSTAP
49.	Shoprite Milk Of Magnesia
50.	Signature Care Mucus Relief Max
51.	Smart Sense Mucus Relief ER
52.	Sound Body Milk of Magnesia
53.	Stratuscare Milk of Magnesia
54.	Stratuscare Milk of Magnesia Cherry
55.	Stratuscare Milk of Magnesia Sugar Free
56.	Sunmark Milk of Magnesia
57.	Sunmark Milk Of Magnesia Mint
58.	Sunmark Milk Of Magnesia Original
59.	Tecentriq
60.	Tobramycin
61.	Topcare Milk of Magnesia
62.	TopCare Mucus ER
63.	Transmucosal Fentanyl Citrate
64.	Up and Up mucus relief
65.	Upravi

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