

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204353Orig1s000

PROPRIETARY NAME REVIEW(S)

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*****

Date of This Review: April 24, 2014
Application Type and Number: NDA 204353
Product Name and Strength: Invokamet (canagliflozin and metformin HCl) tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, 150 mg/1,000 mg
Product Type: Multi-Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Janssen, LLC
Submission Date: March 11, 2014
Panorama #: 2014-17064
DMEPA Primary Reviewer: Mishale Mistry, PharmD, MPH
DMEPA Team Leader: Yelena Maslov, PharmD

Contents

1	INTRODUCTION	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS	2
2.1	Promotional Assessment.....	2
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant	4
4	REFERENCES.....	5
	APPENDICES	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Invokamet, from a safety and promotional 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 sponsor previously submitted the proposed proprietary name, Invokamet on April 30, 2013. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Invokamet acceptable from both a promotional and safety perspective in OSE Review # 2013-1078, dated July 26, 2013.

The sponsor re-submitted the name, Invokamet, with no change in product characteristics since the original NDA submission, for re-review on March 11, 2014, 90 days prior to approval of the NDA.

1.2 PRODUCT INFORMATION

The following product information is provided in the submissions dated April 30, 2013 and March 13, 2014.

- Intended Pronunciation: in voe' ka met
- Active Ingredient: Canagliflozin and Metformin HCl Immediate Release
- Indication of Use: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin. Invokamet can also be used in patients who are already treated with both canagliflozin and metformin.
- Route of Administration: Oral
- Dosage Form: Oral tablets
- Strength: 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, 150 mg/1,000 mg
- Dose and Frequency: Recommended starting dose of 50 mg canagliflozin with 500 mg metformin (or current dose of metformin) twice daily with meals. Maximum recommended dose of 150 mg canagliflozin and 1,000 mg metformin hydrochloride twice daily with meals.
- How Supplied: 60-count (b) (4)
- Storage: Store at 25°C (77°F); excursions permitted to 15° to 30 °C (59° to 86°F). Store in the original container.
- Container and Closure Systems: (b) (4) HDPE bottle with (b) (4), induction seal, and dessicant.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's promotional 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Invokamet in their submission. This proprietary name is comprised of a single word that contains a combination of active ingredients. The first letter string 'Invoka' is representative of the Canagliflozin ingredient (Canagliflozin is marketed under proprietary name "Invokana") and the suffix letter string 'met' represents the metformin ingredient. In a previous review (OSE Review # 2013-1078 dated July 26, 2013), we considered whether the proposed proprietary name represents only one of the active ingredients (canagliflozin) because the proposed proprietary name is comprised of a large portion of the trade name Invokana and thus would be misleading pursuant to 21 CFR 201.6 (b) which states:

The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are states elsewhere in the labeling.

However, the suffix 'met' has consistently been used in proprietary names to represent metformin (e.g., Janumet, Avandamet, Actoplus Met). Thus, we concluded that the name is not misleading because each letter string represents the two active ingredients.

¹USAN stem search conducted on March 19, 2014.

2.2.3 FDA Name Simulation Studies

113 practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Forty-five participants interpreted the name correctly (outpatient n=28, voice n=13, inpatient n=4). Twelve participants misinterpreted the capital letter 'I'; 5 for an 'E' (voice n=5), 4 for a 'D' (outpatient n=4), 2 for an 'S' (outpatient n=2), and 1 for an 'A' (outpatient n=1). Thirteen participants misinterpreted the syllable 'ka' for 'ca' in the voice prescription study. Twenty-nine participants misinterpreted the letter 'k' for an 'h' in the inpatient prescription study. 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, March 19, 2014 e-mail, the Division Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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 $\geq 50\%$ retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	75
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

We note that none of the product characteristics changed from our previous review. Therefore, six names previously evaluated in OSE review # 2013-1078, dated July 26, 2013 will not be re-evaluated (Invokana, Avandamet, Fortamet, Invagesic, Invirase, and Invanz).

Our analysis of the remaining 71 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on April 23, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on April 23, 2014, they stated no additional concerns with the proposed proprietary name, Invokamet.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Lyle Canida, OSE project manager, at 301-796-1637.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 11, 2014 submission are altered, 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>).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment:** For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE 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.²

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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 $\geq 50\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 49\%$.

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will

review these 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 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 (See Table 5).

- 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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to 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 do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?

Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ 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 have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, 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"> ○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg
--------	--

Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names <u>with</u> overlapping or similar strengths or doses.	
	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Invokamet Study (Conducted on March 21, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Invokamet 150/1000 po BID</i></p>	<p>Invokamet 50 mg/500 mg 1 tablet by mouth twice daily #60</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Invokamet 50mg/500mg 1 tablet po twice a day #60</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Invokamet					276 People Received Study 113 People Responded
Total	40	37	36	113	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
ANVOKAMET	1	0	0	1	
DIABETIC MED	0	1	0	1	
DNEVOKAMET	1	0	0	1	
DUOKAMET	1	0	0	1	
DUVOKAMET	1	0	0	1	
DUVOKENAT	1	0	0	1	
ENVOCOMET	0	1	0	1	
ENVOKAMET	0	1	0	1	
ENVOKIMET	0	1	0	1	
EVOKAMET	0	1	0	1	
EVVOCAMET	0	1	0	1	
INKOAMET	1	0	0	1	
INROHAMET	0	0	1	1	
INVAKAMET	2	0	0	2	
INVOAMET	0	1	0	1	
INVOBAMET	1	0	0	1	
INVOCAMET	0	13	0	13	
INVOCOMET	0	1	0	1	
INVOGAMET	0	1	0	1	
INVOHAMENT	0	0	1	1	
INVOHAMET	0	0	19	19	
INVOHAMIET	0	0	1	1	
INVOHANET	0	0	1	1	

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
INVOHANIET	0	0	3	3
INVOHANUT	0	0	4	4
INVOKAMET	28	13	4	45
INVOKANET	1	0	0	1
INVOKANIET	0	0	1	1
INVOKANUT	0	0	1	1
INVOKEMET	0	1	0	1
INVOQAMENT	0	1	0	1
SNVOKAMET	1	0	0	1
SRVAKAMENT	1	0	0	1

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

No.	Proposed name: Invokamet Strength(s): 50 mg/500 mg; 50 mg/1000 mg; 150 mg/500 mg; 150 mg/1000 mg Usual Dose: One tablet twice daily to reach desired dose of canagliflozin and metformin	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Invokamet	100%	Subject of this review.

**Appendix D: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%)
with no overlap or numerical similarity in Strength and/or Dose**

No.	Proposed Name	POCA Score (%)
1.	Benzodent	56%
2.	Invarest	56%
3.	Instacort; Instacort 10	54%
4.	Endacof AC	53%
5.	Nicomide-T	51%
6.	Inon Ace Tablet	50%
7.	(b) (4) ***	50%
8.	Ivadantin	50%
9.	Ivocort	50%
10.	Vandetanib***	50%

Appendix E: Moderately Similar Names (i.e., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	<p>Proposed name: Invokamet</p> <p>Strength(s): 50 mg/500 mg; 50 mg/1000 mg; 150 mg/500 mg; 150 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily to reach desired dose of canagliflozin and metformin</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	Endocet	58%	<ul style="list-style-type: none"> • The names do not appear orthographically similar due to the length of the names (differs by 2 letters), and the letters 'v' and 'm' in Invokamet do not appear similar to the letters 'd' and 'c' in Endocet. • In terms of phonetic differences, Invokamet has four syllables whereas Endocet has three syllables. The second and third syllables in Invokamet do not appear similar to the second syllable in Endocet when spoken.
2.	Inveegam	58%	<ul style="list-style-type: none"> • The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'gam' when scripted or spoken. • In terms of phonetic differences, Invokamet has four syllables whereas Endocet has three syllables. The second and third syllables in Invokamet do not appear similar to the second syllable in Inveegam when spoken.
3.	Anzemet	56%	<ul style="list-style-type: none"> • The names do not appear orthographically similar due to the lengths of the names (differs by 2 letters), and the names begin with different first letters: 'I' will likely not be confused for 'A' when scripted in capital lettering. • The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Anze' when scripted or spoken. • Invokamet has an additional upstroke letter, which is absent in Anzemet.

			<ul style="list-style-type: none"> In terms of phonetic differences, Invokamet has four syllables whereas Anzemet has three syllables.
4.	Indapamide	56%	<ul style="list-style-type: none"> The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'mide' when scripted or when spoken. Indapamide has a downstroke letter, which is absent in Invokamet.
5.	Endacof AC	53%	<ul style="list-style-type: none"> The names do not appear orthographically similar due to the length of the names (differs by 2 letters), and the letters 'v' and 'k' in Invokamet do not appear similar to the letters 'd' and 'c' in Endacof. The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'cof' when scripted or when spoken. In terms of phonetic differences, Invokamet has four syllables whereas Endacon has three syllables.
6.	Endacon-DM	52%	<ul style="list-style-type: none"> The names do not appear orthographically similar due to the length of the names (differs by 2 letters), and the letters 'v' and 'k' in Invokamet do not appear similar to the letters 'd' and 'c' in Endacon. The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'con' when scripted or when spoken. In terms of phonetic differences, Invokamet has four syllables whereas Endacon has three syllables.
7.	Entocort	52%	<ul style="list-style-type: none"> The names do not appear orthographically similar as the letters 'v' and 'k' in Invokamet do not appear similar to the letters 't' and 'c' in Entocort. The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'cort' when scripted or spoken. In terms of phonetic differences, Invokamet has four syllables whereas Entocort has three syllables.
8.	Imagent	52%	<ul style="list-style-type: none"> The names do not appear orthographically similar

			<p>due to the length of the names (differs by 2 letters).</p> <ul style="list-style-type: none"> • The prefixes have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Imag' when scripted or spoken. • Imagent has a downstroke letter, which is absent in Invokamet. • In terms of phonetic differences, Invokamet has four syllables where Imagent has three syllables.
9.	Indo-Lemmon	52%	<ul style="list-style-type: none"> • The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'mon' when written or spoken. • In terms of phonetic differences, the second and third syllables in Invokamet do not appear similar to that of Indo-Lemmon when spoken.
10.	Tagamet	52%	<ul style="list-style-type: none"> • The lengths of the names differ by 2 letters. • The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Taga' when scripted or spoken. • Tagamet has a downstroke letter, which is absent in Invokamet. • In terms of phonetic differences, Invokamet has four syllables whereas Tagamet has three syllables.
11.	Treximet	52%	<ul style="list-style-type: none"> • The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Trex' when scripted or spoken. • In terms of phonetic differences, Invokamet has four syllables whereas Treximet has three syllables.
12.	Cesamet	50%	<ul style="list-style-type: none"> • The lengths of the names differ by two letters. • The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'nvo' does not appear similar to 'esa' when scripted or spoken.

			<ul style="list-style-type: none"> In terms of phonetic differences, Invokamet has four syllables whereas Cesamet has three syllables.
13.	Ibopamine	51%	<ul style="list-style-type: none"> The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'nvo' does appear similar to 'bop' when scripted or spoken. Ibopamine has a downstroke letter, which is absent in Invokamet. Invokamet has an additional upstroke letter, located at the end of the name.
14.	Cinacalcet	50%	<ul style="list-style-type: none"> The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'nvo' does not appear similar to 'ina' when scripted or spoken.
15.	Endocodone	50%	<ul style="list-style-type: none"> The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'done' when scripted or spoken.
16.	Endodan	50%	<ul style="list-style-type: none"> The lengths of the names differ by two letters. The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'dan' when scripted or spoken. In terms of phonetic differences, Invokamet has four syllables whereas Endodan has three syllables.
17.	Endometrin	50%	<ul style="list-style-type: none"> The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'trin' when scripted or spoken.
18.	Enterocote	50%	<ul style="list-style-type: none"> The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'vo' does not appear similar to 'ter' when scripted or spoken. The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'met' does not appear similar to 'cote' when scripted or spoken. In terms of phonetic differences, Invokamet has four syllables whereas Enterocote has three

			syllables.
19.	Evamist	50%	<ul style="list-style-type: none"> The names do not appear orthographically similar due to the length of the names (differs by 2 letters), and the letter 'v' in Invokamet does not appear similar to the letter 'a' in Evamist. The presence of the infix 'oka' in Invokamet also creates additional orthographic and phonetic differences to minimize confusion from Evamist. In terms of phonetic differences, Invokamet has four syllables whereas Evamist has three syllables.
20.	Foscarnet	50%	<ul style="list-style-type: none"> The names begin with different first letters: 'I' will likely not be confused for 'F' when scripted. The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Fos' when scripted or spoken. In terms of phonetic differences, Invokamet has four syllables whereas Foscarnet has three syllables.
21.	Inositech	50%	<ul style="list-style-type: none"> The infixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'voka' does not appear similar to 'osi' when scripted or spoken.
22.	Novacet	50%	<ul style="list-style-type: none"> The lengths of the names differ by two letters. The names begin with different first letters: 'I' will likely not be confused for 'N' when scripted. The prefixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'Invo' does not appear similar to 'Nova' when scripted or spoken. Invokamet has two additional upstroke letters, which are absent in Novacet. In terms of phonetic differences, Invokamet has four syllables whereas Novacet has three syllables.
23.	Rondameth	50%	<ul style="list-style-type: none"> The names begin with different first letters: 'I' will likely not be confused for 'R' when scripted. The prefixes of the names have sufficient orthographic and phonetic differences to minimize

			<p>confusion: 'Invo' does not appear similar to 'Ronda' when scripted or spoken.</p> <ul style="list-style-type: none"> In terms of phonetic differences, Invokamet has four syllables whereas Rondameth has three syllables.
--	--	--	--

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

No.	Name	POCA Score (%)	Failure Preventions
1.	Invokamet	100%	Subject of this review.
2.	(b) (4) ***	68%	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3224). Product approved under new proprietary name Invokana.
3.	(b) (4) ***	62%	Proposed Proprietary Name found unacceptable by DMEPA (b) (4) Application withdrawn by the applicant.
4.	Enzacamene	60%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Indoramim	60%	Established name for international product marketed in Europe.
6.	Glucamet	58%	International product marketed in UK.
7.	(b) (4) ***	58%	Proposed Proprietary Name found unacceptable by DMEPA (b) (4) Application withdrawn by the applicant.
8.	Lincomed	56%	Veterinary product.
9.	Endoxana	55%	International product marketed in Ireland, Thailand, and UK.
10.	Isoket	55%	International product marketed in Mexico, South Africa, Venezuela, Hong Kong, Israel, Malaysia, Phillipines, Portugal, Germany, Ireland, Thailand, Austria, China, Czech Republic, Switzerland, UK, Ukraine.
11.	(b) (4) ***	55%	Proposed Proprietary Name found unacceptable by DMEPA (b) (4) Product approved under new proprietary name Caprelsa.

12.	Cefetamet	54%	Established name for international product marketed in India, China, Portugal, Austria, Brazil, Germany, Hong Kong, Italy, Mexico, Switzerland, Greece, Poland.
13.	Infestat	54%	International product marketed in UK.
14.	(b) (4) ***	54%	This is a primary proposed proprietary name and the product was approved under the secondary proprietary name (b) (4). Both names were considered acceptable by DMEPA (b) (4).
15.	Indomod	53%	International product marketed in Ireland and UK.
16.	Ivomec	53%	Veterinary product.
17.	(b) (4) ***	52%	Proposed Proprietary Name found acceptable by DMEPA (b) (4). No additional information provided.
18.	(b) (4) ***	52%	This is a secondary proposed proprietary name (b) (4) (b) (4) and DMEPA found the primary proposed name acceptable (b) (4). Application withdrawn by the applicant.
19.	Clindamed	52%	Veterinary product.
20.	Cotameth	52%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Dyspamet	52%	International product marketed in Ireland and UK.
22.	Endoxan	52%	International product marketed in 29 countries outside of the United States.
23.	(b) (4) ***	52%	Proposed Proprietary Name found unacceptable by DMEPA (b) (4). Product approved under new proprietary name Kapvay.
24.	Indomax	52%	International product marketed in UK.
25.	(b) (4) ***	52%	Proposed Proprietary Name found unacceptable by DMEPA and name withdrawn by the Applicant. The product was approved under the proprietary name Ofirmev.
26.	(b) (4) ***	52%	Proposed Proprietary Name found unacceptable by DMEPA and name withdrawn by the Applicant based upon preliminary feedback (b) (4). The product was approved under the proprietary name Ofirmev.

27.	(b) (4) ***	52%	Proposed Proprietary Name withdrawn by the Applicant. The product was approved under the proprietary name Kazano.
28.	Nystamont	52%	International product marketed in Greece and UK.
29.	Fenoket	51%	International product marketed in UK.
30.	(b) (4) ***	51%	This is a tertiary proposed proprietary name and the product was approved under the name Zelboraf.
31.	Doxatet	50%	International product marketed in UK.
32.	Galenamet	50%	International product marketed in Ireland and UK.
33.	(b) (4) ***	50%	This is a primary proposed proprietary name considered acceptable by DMEPA (b) (4) Application withdrawn by the applicant.
34.	Indobufen	50%	Established name for international product marketed in Austria, Czech Republic, Italy, Mexico, Portugal, Venezuela, China.
35.	Iodoxamid	50%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	(b) (4) ***	50%	Name entered by Safety Evaluator. Unable to find name in AIMS/Panorama/L:Drive (no Application #). International product marketed in Japan.
37.	Noctamid	50%	International product marketed in Germany, France, Italy, Portugal, Austria, Belgium, Greece, Ireland, Netherlands, New Zealand, South Africa, Spain, Switzerland.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MISHALE P MISTRY
04/24/2014

YELENA L MASLOV
04/25/2014

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: July 26, 2013

Reviewer: Reasol S. Agustin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Invokamet (Canagliflozin and Metformin HCl) Tablets,
50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, and
150 mg/1000 mg

Application Type/Number: NDA 204353

Applicant/Sponsor: Janssen

OSE RCM #: 2013-1078

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1	INTRODUCTION.....	1
1.1	Product Information.....	1
2	RESULTS.....	1
2.1	Promotional Assessment	2
2.2	Safety Assessment	2
3	CONCLUSIONS	5
3.1	Comments to the Applicant	5
4	REFERENCES	6
	APPENDICES	9

1 INTRODUCTION

This review evaluates the proposed proprietary name, Invokamet (Canagliflozin and Metformin HCL) Tablets, NDA 204353, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the April 30, 2013 proprietary name submission.

- Active Ingredient: Canagliflozin and Metformin HCL
- Indication of Use: Treatment of type 2 diabetes mellitus
- Route of Administration: Oral
- Dosage Form: Fixed dose combination tablets
- Strength: 50 mg/500 mg, 50 mg, 1000 mg, 150 mg/500 mg, and 150 mg/1000 mg
- Dose and Frequency: One tablet twice daily to reach the desired dose of canagliflozin and metformin. Maximum daily dose of 300 mg canagliflozin and 2000 mg metformin.
- How Supplied: Bottle of 60 tablets (b) (4)
- Storage: Store at room temperature between 68°F to 77°F (20°C to 25°C). Store in original container
- Container and Closure Systems: (b) (4)
induction seal, and desiccant (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products concurred with the findings of OPDP's promotional 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

The May 8, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated that the proposed name, Invokamet, has no intended meaning or derivation. This proprietary name is comprised of a single word. However, the word has two letter strings. The first letter string ‘Invoka’ is representative of the Canagliflozin ingredient (Canagliflozin is marketed under proprietary name “Invokana”) and the suffix letter string ‘met’ represents the metformin ingredient. We considered whether the name represents only one of the active ingredients (canagliflozin) because a large portion of the trade name Invokana and thus would be misleading pursuant to 21 CFR 201.6 (b) which states:

The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

However, the suffix ‘met’ has consistently been used in proprietary names to represent metformin (e.g., Janumet, Avandamet, Actoplus Met). Thus, we conclude that the name is not misleading because each letter string represents the two active ingredients.

2.2.3 Postmarketing Medication Error Data Evaluated For Product Line Extension

DMEPA is aware that combination antidiabetic names and their single active ingredient names have been identified as sources of drug name confusion. In order to evaluate the medication error risk due to potential confusion between the single-ingredient product, Invokana, and this combination product, Invokamet, we considered the historic confusion with similar antidiabetic products that use a modified version of the root name of a single active ingredient product and a suffix “met”.

Previous DMEPA reviews evaluated the name pairs Avandia vs. Avandamet, Januvia vs. Janumet, and Actos vs. Actoplus Met. The FDA Adverse Event Reporting System (FAERS) search terms used in those reviews are described in Table 1.

Table 1: FAERS Search Strategy	
Date	7/12/2011-6/25/13
Drug Names	Trade name: Januvia and Janumet Trade name: Avandia and Avandamet Trade name: Actos and Actoplus Met
MedDRA Search Strategy	Medication Errors (HLGT) Product Packaging Issues HLT Product Label Issues HLT Product Quality Issues (NEC) HLT

This search identified confirmed reports of confusion between the single ingredient and combination products, the majority of which occurred with Januvia and Janumet and Avandia and Avandamet. Avandia and Avandamet are listed in the USP's Drug Error Finder as Look-alike/Sound-alike Drug Names. Januvia and Janumet are listed in ISMP's List of Confused Drug Names. These name pairs are not only similar in appearance and sound but overlap in strength (see Table 2). However, in the case of Invokana and Invokamet, although there are orthographic and phonetic similarities, there is no overlap in strengths which helps mitigate the risk for confusion. Thus, even if Invokamet is thought to be Invokana, the differences in strength will prevent the confusion between these products. As a result, we do not find the construct of this name permissible.

Table 2

Single Ingredient vs. Combination	Strengths for Single Ingredient	Strengths for Combination
Invokana vs. Invokamet	100 mg, 300 mg	50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg
Januvia vs. Janumet	25 mg, 50 mg, 100 mg	50 mg/500 mg, 50 mg/1000 mg
Avandia vs. Avandamet	2 mg, 4 mg, 8 mg	2 mg/500 mg, 2 mg/1000 mg, 4 mg/500 mg, 4 mg/1000 mg

2.2.4 FDA Name Simulation Studies

Seventy practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Ten of the 25 inpatient participants responded correctly and the most common misinterpretation occurred with 8 participants misinterpreting the letter string 'nv' for 'm' (i.e. INVokamet

misinterpreted as ‘IM_o). Two of the 19 voice participants responded correctly and a common misinterpretation occurred with 11 participants misinterpreting the letter ‘k’ for ‘c’ (i.e. InvoKamet misinterpreted as ‘Cam’). Three of the 19 outpatient participants responded correctly and the most common misinterpretation occurred with 7 participants misinterpreting the letter ‘a’ for ‘e’ (i.e. InvokAmet misinterpreted as ‘InvokEm) and 4 participants misinterpreting the letter string ‘nv’ for ‘m’ (i.e. INVokamet misinterpreted as ‘IM_o). We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results of the the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 21, 2013 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters considered in the search for similar names to the proposed proprietary name, Invokamet.

For this review, we also evaluated the previously identified names from the Invokana review OSE #2012-91689 since Invokamet begins with the same 6 letters “Invoka” (See Table 1). Our analysis of the forty-two names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 42 names will not pose a risk for confusion as described in Appendices D through E.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Invokana [♦]	EPD	Isentress	EPD	Invirase	EPD
Invanz	EPD	Invagesic	EPD	Invigorex	EPD
Inomax	EPD	Icatibant	EPD	Imatinib	EPD
Imuhance	SE	Insulase	SE	Janumet	SE
Leukeran	SE	Irinotecan	SE	Inversine	SE
Leukine	SE	Jevtana	SE	Juvederm	SE
Terbinex	SE	Jentadueto	SE	Jantoven	SE

[♦] See Section 2.2.3 for discussion of Invokana and Invokamet

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)

Lactinex	SE	Tindamax	SE	Tensilon	EPD
Insul-eze	EPD	Imodium A-D	EPD	Invega	EPD
Evoxac	EPD	Januvia	FDA	Innopran XL	EPD
Ivermectin	EPD	Imuran	FDA	Enulose	EPD
Teveten	EPD	Gardasil	EPD	Femtrace	EPD
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Invokamet	EPD	Vokamet	EPD	Invokanamet	EPD
Envokahna	EPD	Envokana	EPD	Avandamet	SE
Fortamet	SE				

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on June 20, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on July 1, 2013, they stated no additional concerns with the proposed proprietary name, Invokamet.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your April 30, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. Red Book (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. Medical Abbreviations (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Invokamet	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘I’	cl, J, L, T	any vowel
lowercase ‘i’	e, l	any vowel
lowercase ‘n’	h, m, r, s, u, x	gn, kn, m, mn, pn
lowercase ‘v’	n, r, u, y	b, f, d
lowercase ‘o’	a, c, e, u	any vowel, ol
lowercase ‘k’	x, h, la	c, g
lowercase ‘a’	ci, ce, cl, d, el, o, u, e, i	any vowel
lowercase ‘m’	rn, nn, n, v, w, wi, vi, onc, z, r, nu	
lowercase ‘e’	a, i, l, o, u, p	any vowel
lowercase ‘t’	r, f, x, a	D
Letter strings		
et	d	
Vo	n	
nv	nr, mi, m	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Invokamet Study (Conducted on May 10, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Invokamet 150mg/500mg bid</i></p>	<p>Invokamet 50 mg/500 mg 1 tablet by mouth twice daily #60</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Invokamet 50mg/500mg 1 tab BID #60</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Invokamet

As of Date 6/5/2013

191 People Received Study

63 People Responded

Study Name: Invokamet

	Total	19	19	25	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
ENDOCAMET	0	1	0	1	
IMOKAMERT	0	0	1	1	
IMOKAMET	2	0	4	6	
IMOKANUT	0	0	1	1	
IMOKIMET	1	0	0	1	
IMOKUMET	1	0	0	1	
IMOKUNET	0	0	1	1	
IMVOKANUET	0	0	1	1	
INDOLCAMET	0	2	0	2	

INNOKOMET	1	0	0	1
INOVKAMET	0	0	1	1
INVOCAMED	0	1	0	1
INVOCAMET	0	7	0	7
INVOGAMET	0	1	0	1
INVOKAMET	3	2	10	15
INVOKAMIT	0	0	3	3
INVOKANET	0	0	1	1
INVOKANRET	0	0	1	1
INVOKANUT	0	0	1	1
INVOKEMENT	1	0	0	1
INVOKEMET	5	0	0	5
INVOKERMET	1	0	0	1
INVOKIMET	0	2	0	2
INVOKOMET	0	1	0	1
INVOKUMET	3	0	0	3
INVOKUVET	1	0	0	1
INVOLCAMED	0	1	0	1
INVOLKAMET	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name		Active Ingredient	Similarity to Invokamet	Failure preventions
1	Invokamet	Canagliflozin and Metformin	Look and Sound alike	This name is the subject of this review.
2	Vokamet		Look and Sound alike	Name identified in USPTO (b) (4). Unable to find product characteristics in commonly used drug databases.
3	Invokanamet		Look and Sound alike	Name identified in USPTO (b) (4). Unable to find product characteristics in commonly used drug databases.
4	Envokahna		Look and Sound alike	Name identified in USPTO (b) (4). Unable to find product characteristics in commonly used drug databases.
5	Envokana		Look and Sound alike	Name identified in USPTO (b) (4). Unable to find product characteristics in commonly used drug databases.
4	Invanz	Ertapenem	Look like	The pair have sufficient orthographic differences
5	Inomax	Nitric Oxide	Look alike	The pair have sufficient orthographic differences
6	Leukine	Sargramostim	Look alike	The pair have sufficient orthographic differences
7	Jevtana	Cabazitaxel	Look alike	The pair have sufficient orthographic differences
8	Jantoven	Warfarin	Look alike	The pair have sufficient orthographic differences
9	Femtrace	Estradiol Acetate	Look alike	The pair have sufficient orthographic differences
10	Gardasil	Human Papillomavirus (HPV) Quadrivalent Recombinant Vaccine	Look alike	The pair have sufficient orthographic differences

11	Teveten	Eprosartan	Look alike	The pair have sufficient orthographic differences
12	Isentress	Raltegravir	Look alike	The pair have sufficient orthographic differences
13		Icatibant	Look alike	The pair have sufficient orthographic differences
14	Imuhance	Nutriceutical	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
15	Jentaducto	Linagliptin and Metformin HCl	Look	The pair have sufficient orthographic differences
16	Lactinex	L. acidophilus and L. bulgaris	Look	The pair have sufficient orthographic differences
17	Insul-eze	Medical device	Look	Product is not a drug; it is a medical device
18	Invega	Paliperidone	Look	The pair have sufficient orthographic differences
19	Evoxac	Cevimeline HCL	Look	The pair have sufficient orthographic differences
20	Januvia	Sitagliptin	Look	The pair have sufficient orthographic differences
21		Ivermectin	Look	The pair have sufficient orthographic differences
22		Enulose	Look	The pair have sufficient orthographic differences
23	Tensilon	Edrophonium Chloride	<i>Look</i>	The pair have sufficient orthographic differences

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin) Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>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</p>
<p>1</p>	<p>Invokana (Canagliflozin) Dosage form and Strength(s): Oral tablets: 100 mg and 300 mg Usual dose: One tablet (100 mg or 300 mg) by mouth once daily</p>	<p>Orthographic similarity: Both names begin with the letter strings ‘Invoka’ and the letter strings ‘me’ and ‘na’ appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral tablets.</p>	<p>Orthographic difference: Invokamet ends with an upstroke ‘t’ which is absent in Invokana, which may help in differentiating the two names. Strength: Both Invokamet and Invokana are available in multiple strengths. Invokamet is a fixed-dose combination product that will require both strengths for a complete prescription. There is no numerical overlap or similarity between the strengths during prescription writing.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
2	<p>Janumet (Sitagliptin and Metformin)</p> <p>Dosage Form and Strength: Oral tablets: 50 mg/500 mg, 50 mg/1000 mg XR: 50 mg/500 mg, 50 mg/1000 mg, 100 mg/1000 mg</p> <p>Usual dose: IR: 1 tablet by mouth twice daily; XR: 1 tablet by mouth once daily.</p> <p>Usual dose: 1 tablet by mouth twice daily</p>	<p>Orthographic similarity: The beginning letter ‘J’ and ‘I’ appear orthographically similar when scripted. In addition, both names end with the letter string ‘met’</p> <p>Dosage form and route of administration: Both are available as oral tablets</p> <p>Strength: Both Invokamet and Janumet are fixed dose combination products available in multiple strengths. There is numerical overlap between the strengths (50 mg/500 mg, 50 mg/1000 mg).</p> <p>Frequency: Both are prescribed as twice daily.</p>	<p>Orthographic difference: Invokamet contains an additional upstroke ‘k’ in position 5 which is absent in Janumet, giving the names different shapes. In addition, the letter strings ‘nvoka’ appear orthographically longer and different from ‘anu’ when scripted.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
3	<p>Invirase (Saquinavir)</p> <p>Dosage form and strength: Oral capsule: 200 mg Oral tablets: 500 mg</p> <p>Usual dose: 1,000 mg orally 2 times daily with ritonavir 100 mg</p>	<p>Orthographic similarity: Both names begin with the letter string ‘Inv’ and the letter strings ‘ame’ and ‘ase’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: Invokamet contains 2 upstrokes, ‘k’ in position 5 and ‘t’ in the last position, which is absent in Invirase, giving the names different shapes.</p> <p>Strength: Both Invokamet and Invirase are available in multiple strengths. Although there is numerical overlap between one of the strengths (500 mg), Invokamet is a fixed-dose combination product and will require both strengths for a complete prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
4	<p>Leukeran (Chlorambucil)</p> <p>Dosage form and strength: Oral tablet: 2 mg</p> <p>Usual dose: 0.1 to 0.2 mg/kg daily for 3 to 6 weeks. This usually amounts to 4 to 10 mg/day for the average patient. The entire daily dose may be given at one time.</p>	<p>Orthographic similarity: The beginning letters ‘T’ and ‘L’ and ‘v’ and ‘u’ appear orthographically similar when scripted. In addition, both names contain an upstroke ‘k’ in similar positions.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: Invokamet ends with an upstroke ‘t’ which is absent in Leukeran, giving the names different shapes and making the ending letter strings ‘amet’ and ‘eran’ appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. Invokamet is a fixed-dose combination product available in multiple strengths, thus will require both strengths for a complete prescription vs. Leukeran is available in single strength and may be omitted from a prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
5	<p>Irinotecan</p> <p>Dosage form and strength: Intravenous solution: 40 mg/2 mL, 100 mg/5 mL, and 500 mg/25 mL</p> <p>Usual dose: Regimen 1: 6-wk cycle with bolus 5-fluorouracil and leucovorin (next cycle begins n day 43): 5 mg/m² intravenously over 90 min, days 1, 8, 15, 22. Dose = 8 mg to 9.5 mg based on average adult body surface area (BSA) of 1.6 m² to 1.9 m²</p> <p>Regimen 2: 6-wk cycle with 5-fluorouracil/leucovorin (next cycle begins on day 43): 180 mg/m² IV over 90 min, days 1, 15, 29. Dose = 288 mg to 342 mg based on average adult body surface area (BSA) of 1.6 m² to 1.9 m²</p>	<p>Orthographic similarity: The beginning letter strings ‘In’ and ‘Iri’ and the letter strings ‘vo’ and ‘no’ appear orthographically similar when scripted. In addition, both names contain the upstroke letters ‘k’ vs. ‘t’ in the similar positions.</p>	<p>Orthographic difference: Invokamet ends with an upstroke ‘t’ which is absent in Irinotecan, giving the names different shapes and making the ending letter strings ‘amet’ and ‘eran’ appear orthographically different when scripted.</p> <p>Strength: Both Invokamet and Irinotecan are available in multiple strengths. Although there is numerical overlap (500 mg) and similarity (1000 mg vs. 100 mg) between one of the strengths, Invokamet is a fixed-dose combination product and will require both strengths for a complete prescription.</p> <p>Frequency: Invokamet is prescribed twice daily vs. Irinotecan is prescribed on specific days (i.e. Day 1, 8, etc) over a 6 week cycle</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
6	<p>Insulase (Chlorpropamide)</p> <p>Dosage form and strength: Oral tablet: 100 mg and 250 mg</p> <p>Usual dose: 250 mg orally daily</p>	<p>Orthographic similarity: Both names contain the beginning letter strings ‘In’ and contain the upstroke letters ‘k’ vs. ‘l’ in the same positions. In addition, the letter strings ‘ame’ and ‘ase’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p>	<p>Orthographic difference: Invokamet ends with an upstroke ‘t’ which is absent in Insulase, which may help in differentiating the two names.</p> <p>Strength: Both Invokamet and Insulase are available in multiple strengths. Although there is numerical similarity (1000 mg vs. 100 mg) between one of the strengths, Invokamet is a fixed-dose combination product and will require both strengths for a complete prescription.</p> <p>***Preliminary usage data shows Insulase is not in sig database (b) (4) Insulase was found in the name database (b) (4), but no prescription information returned from the search.</p>

	<p>Proposed name: Invokamet (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
7	<p>Inversine (Mecamylamine Hydrochloride)</p> <p>Dosage form and strength: Oral tablets: 2.5 mg</p> <p>Usual dose: 2.5 mg orally twice daily. Average dose: 25 mg/day in divided doses.</p>	<p>Orthographic similarity: The beginning letter strings ‘Invo’ and ‘Inve’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p> <p>Dosage form and route of administration: Both are prescribed as twice daily</p>	<p>Orthographic difference: Invokamet contains 2 upstrokes, ‘k’ in position 5 and ‘t’ in the last position, which is absent in Inversine, giving the names different shapes. In addition, the ending letter strings ‘kamet’ and ‘sine’ appear orthographically different when scripted.</p> <p>Strength: <i>Multiple vs. single.</i> Invokamet is a fixed-dose combination product available in multiple strengths, thus will require both strengths for a complete prescription vs. Inversine is available in single strength and may be omitted from a prescription.</p>

	<p>Proposed name: Invokamet (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
8	<p>Juvederm Ultra and Ultra Plus (Hyaluronic acid): Intradermal gel: 24 mg/mL</p> <p>Juvederm Ultra Plus XC and Ultra XC: Intradermal gel: Hyaluronic acid 24 mg/mL and Lidocaine 0.3 %</p> <p>Usual dose: Inject as required for cosmetic result; typical treatment regimen requires 1.6 mL/treatment site; typical volume for repeat treatment is 0.7 mL per treatment site; maximum: 20 mL/60 kg/year</p>	<p>Orthographic similarity: The beginning letter strings ‘Invo’/ ‘Juve’ and ‘ame’/’erm’ appear orthographically similar when scripted. In addition, both names contain the upstroke letters ‘k’ vs. ‘l’ in the same positions.</p>	<p>Orthographic difference: Invokamet ends with an upstroke ‘t’ which is absent in Juvederm, which may help in differentiating the two names. In addition, Juvederm is available in multiple formulations and requires a modifier for a complete prescription.</p> <p>Strength: Multiple vs. single. Invokamet is available in multiple strengths and will require strength for a complete prescription vs. Juvederm is available in single strength and may be omitted from a prescription.</p> <p>Dosage form and route of administration: Invokamet is available as a tablet given orally vs. Juvederm is available as a gel given intradermally.</p> <p>Frequency: Invokamet is prescribed twice daily vs. Juvederm is prescribed as needed.</p>

	<p>Proposed name: Invokamet (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
9	<p>Invagesic* (Aspirin, Caffeine, and Orphenadrine)</p> <p>Dosage form and strength: Oral tablets: 385 mg/30 mg/25 mg</p> <p>Usual dose: Usual Dose: 1 or 2 tablets 3 or 4 times daily</p> <p><i>*Available as Norgesic (reference listed drug)</i></p>	<p>Orthographic similarity: The beginning letter strings ‘Invo’ and ‘Inva’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p>	<p>Orthographic difference: Invokamet contains 2 upstrokes, ‘k’ in position 5 and ‘t’ in the last position, whereas Invagesic contains a downstroke ‘g’ in the same position, giving the names different shapes. In addition, the ending letters strings ‘amet’ and ‘esic’ appear orthographically different when scripted.</p> <p>Strength: <i>Multiple vs. single.</i> Invokamet is a fixed-dose combination product available in multiple strengths, thus will require both strengths for a complete prescription vs. Invagesic is available in single strength and may be omitted from a prescription.</p> <p>Frequency: Invokamet is prescribed twice daily vs. Invagesic is prescribed 3 to 4 times daily.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
10	<p>Avandamet (Rosiglitazone and Metformin)</p> <p>Dosage form and strength: Oral tablets: FDC: 2 mg/500 mg, 4 mg/500 mg, 2 mg/1000 mg, 4 mg/1000 mg</p> <p>Usual dose: 1 tablet by mouth twice daily</p>	<p>Orthographic similarity: Both names contain the ending letter string ‘amet’ and contain the upstroke letters 'k' vs. 'd' in similar positions.</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p> <p>Frequency: Both are prescribed as twice daily</p>	<p>Orthographic difference: The beginning letter strings ‘Invo’ and ‘Avan’ appear orthographically different when scripted.</p> <p>Strength: Both Invokamet and Avandamet are fixed dose combination products available in multiple strengths. Although there is numerical overlap between one of the strengths (500 mg and 1000 mg), both products will require both strengths for a complete prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
11	<p>Fortamet (Metformin HCl Extended-release)</p> <p>Dosage form and strength: Oral tablets: 500 mg, 1000 mg</p> <p>Usual dose: 1 tablet by mouth once daily</p>	<p>Orthographic similarity: The beginning letter ‘I’ and ‘F’ appear orthographically similar when scripted. In addition, both names contain the upstroke letters ‘k’ vs. ‘t’ in similar positions and end with the letter string ‘amet’</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The letter strings ‘nvo’ and ‘or’ appear orthographically different when scripted.</p> <p>Strength: Both Invokamet and Fortamet are available in multiple strengths. Although there is numerical overlap between one of the strengths (500 mg and 1000 mg), Invokamet is a fixed-dose combination product and will require both strengths for a complete prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
12	<p>Imatinib</p> <p>Dosage form and strength: Oral tablets: 100 mg, 400 mg</p> <p>Usual dose: 1 tablet by mouth once daily</p>	<p>Orthographic similarity: The beginning letter strings ‘Invo’ and ‘Ima.’ In addition, both names contain 2 upstroke letters ‘k’ / ‘t’ and ‘t’/’b’ in the same positions, giving the names similar shapes.</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The letter string ‘ame’ appear orthographically longer and different from ‘ini’ when scripted.</p> <p>Strength: Both Invokamet and Imatinib are available in multiple strengths. Although there is numerical similarity between one of the strengths (1000 mg vs. 100 mg), Invokamet is a fixed-dose combination product and will require both strengths for a complete prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
13	<p>Tindamax (Tinidazole)</p> <p>Dosage Form and Strength: Oral tablet: 250 mg, 500 mg</p> <p>Usual dose: 2 gm by mouth once daily for 3 to 5 days</p>	<p>Orthographic similarity: The beginning letters 'I' / 'T' and ending letter strings 'amet' / 'amax' appear orthographically similar when scripted. In addition, both names contain the upstroke letters 'k' vs. 'd' in similar positions.</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The letter string 'nvo' appear orthographically longer and different from 'in' when scripted.</p> <p>Strength: Both Invokamet and Tindamax are available in multiple strengths. Although there is numerical overlap between one of the strengths (500 mg), Invokamet is a fixed-dosed combination product and will require both strengths for a complete prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
14	<p>Terbinex (Hydroxypropyl Chitosan and Terbinafine HCl)</p> <p>Dosage Form and Strength: Combination kit: 1%/250 mg</p> <p>Usual dose: 1 tablet by mouth once daily</p>	<p>Orthographic similarity: The beginning letters 'I' / 'T' and ending letter strings 'met' / 'nex' appear orthographically similar when scripted. In addition, both names contain the upstroke letters 'k' vs. 'b' in similar positions.</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The letter strings 'nvo' appear orthographically longer and different from 'er' when scripted. In addition, the letter 'a' and 'I' appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. Invokamet is a fixed-dose combination product available in multiple strengths thus will require both strengths for a complete prescription vs. Terbinex is available in single strength and may be omitted from a prescription.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
15	<p>Invigorex (Vitamin B6, Niacin, Vitamin E, Zinc, L-Arginine HCl, Tribulus Terrestris, Muira Puama, Jujube, Avena Sativa, Maca, Stinging Nettle, Horny Goat Weed, Siberian Ginseng, Saw Palmetto)</p> <p>Dosage Form and Strength: Oral capsules: no strength</p> <p>Usual dose: no information</p>	<p>Orthographic similarity: Both names begin with the letters ‘Inv’ and the ending letter strings ‘amet’ / ‘orex’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms</p>	<p>Orthographic difference: Invokamet contains an upstroke ‘k’ in position 5 whereas Invigorex contains a downstroke ‘g’ in the same position, giving the names different shapes.</p> <p>Strength: Multiple vs. no strength. Invokamet is a fixed-dose combination product available in multiple strengths thus will require both strengths for a complete prescription vs. Invigorex does not have a strength.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
16	<p>Imodium A-D (Loperamide)</p> <p>Dosage form and strength: Oral tablets or capsule: 2 mg Oral liquid: 1 mg/7.5 mL</p> <p>Usual dose: Adults: 4 mg after the first loose stool then 2 mg after each subsequent loose stool. Clinical improvement is usually observed within 48 hours Children: 15 ml (3 teaspoon) or 30 mL (6 teaspoon) after first loose stool followed by 7.5 mL (1.5 teaspoon) to 15 ml (3 teaspoon) after each loose stool</p>	<p>Orthographic similarity: The beginning letter strings ‘Inv’ and ‘Imo’ appear orthographically similar when scripted. In addition, both names contain the upstroke letters ‘k’ vs. ‘d’ in similar positions.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: Invokamet contains an upstroke ‘t’ at the end of the name which is absent in Imodium, giving the names different shapes and making the ending letter strings ‘amet’ and ‘ium’ appear orthographically different when scripted.</p> <p>Strength: Both Invokamet and Imodium are available in multiple strengths. There is no overlap between the strengths.</p> <p>Dosing: There is no numerical overlap in dosing.</p> <p>Frequency: Invokamet is prescribed twice daily vs. Imodium is prescribed as needed.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
17	<p>Innopran XL (Propranolol Sustained-Release Beads)</p> <p>Dosage form and strength: Extended-release 24 hour Oral Capsules: 80 mg and 120 mg</p> <p>Usual dose: 80 mg once daily at bedtime (approximately 10 PM). Titration may be needed to a dose of 120 mg. The time needed for full antihypertensive response is variable but is usually achieved within 2 to 3 weeks.</p>	<p>Orthographic similarity: The begging letter strings ‘Invo’ and ‘Inno’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: Invokamet contains 2 upstrokes, ‘k’ in position 5 and ‘t’ in the last position, whereas Innopran contains a downstroke ‘p’ in the position 5, giving the names different shapes and making the endingletter strings ‘kamet’ and ‘pran’ appear orthographically different when scripted.</p> <p>Strength: Both are available in multiple strengths and need to be specified for a complete prescription; there is no overlap between the strengths.</p>

	<p>Proposed name: <i>Invokamet</i> (Canagliflozin and Metformin)</p> <p>Dosage form and Strength(s): Fixed dose combination (FDC) Oral tablets: 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, 150 mg/1000 mg</p> <p>Usual dose: One tablet by mouth twice daily (Maximum dose: 300 mg/2000 mg)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
18	<p>Imuran (Azathioprine)</p> <p>Dosage form and strength: Oral tablet: 50 mg, 100 mg</p> <p>Usual dose: 100 mg (1 tablet) by mouth once daily</p>	<p>Orthographic similarity: The beginning letter ‘Invo’ and ‘Imu’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: Invokamet (9 letters) appear orthographically longer than Imuran (6 letter). In addition, Invokamet contains 2 upstrokes, ‘k’ in position 5 and ‘t’ in the last position, which is absent in Imuran giving the names different shapes and making the ending letter strings ‘ran’ and ‘kamet’ appear orthographically different when scripted.</p> <p>Strength: Both Invokamet and Imuran are available in multiple strengths. Although there is numerical overlap (50 mg) and similarity (1000 mg vs. 100 mg) between one of the strengths, Invokamet is a fixed-dosed combination product and will require both strengths for a complete prescription.</p>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

REASOL AGUSTIN
07/26/2013

YELENA L MASLOV
07/26/2013

CAROL A HOLQUIST
07/26/2013