

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206073Orig1s000**

**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\*\*\***

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<b>Date of This Review:</b>	May 7, 2014
<b>Application Type and Number:</b>	NDA 206073
<b>Product Name and Strength:</b>	Glyxambi (empagliflozin and linagliptin) 10 mg/5 mg; 25 mg/5 mg
<b>Product Type:</b>	Multi-ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Boehringer Ingelheim Pharmaceuticals, Inc
<b>Submission Date:</b>	March 13, 2014
<b>Panorama #:</b>	2014-17094
<b>DMEPA Primary Reviewer:</b>	Mishale Mistry, PharmD, MPH
<b>DMEPA Team Leader:</b>	Yelena Maslov, PharmD

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Glyxambi, 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 PRODUCT INFORMATION

The following product information is provided in the March 13, 2014 proprietary name submission and January 30, 2014 Original NDA submission.

- Intended Pronunciation: glik-SAM-bee
- Active Ingredient: empagliflozin and linagliptin
- Indication of Use: Adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate.
- Route of Administration: Oral
- Dosage Form: Oral fixed-dose combination (FDC) tablets
- Strength: 10 mg empagliflozin/5 mg linagliptin, 25 mg empagliflozin/5 mg linagliptin
- Dose and Frequency: Recommended starting dose is 10 mg empagliflozin/5 mg linagliptin once daily. Dose can be increased to 25 mg empagliflozin/5 mg linagliptin once daily in patients who require additional control.
- How Supplied:
  - 10 mg/5 mg tablets: Pale yellow, arc triangular, flat-faced, bevel-edged, film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol; the other side is debossed with “10/5”. Bottles of 30-count, 90-count, 1000-count, 30-tablet institutional pack, 7-tablet professional sample bottle.
  - 25 mg/5 mg tablets: Pale pink, arc triangular, flat-faced, bevel-edged, film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol; the other side is debossed with “25/5”. Bottles of 30-count, 90-count, 1000-count, 30-tablet institutional pack, 7-tablet professional sample bottle.
- Storage: Store at 25°C (77 °F); excursions permitted to 15°C - 30°C (59°F-86 °F). Store in a safe place out of reach of children.
- Container and Closure Systems:

- Multidose high density polyethylene (HDPE) bottle (60 cc and 375 cc), closed with a two piece (b) (4) closure with an induction seal liner
- Blister card consists of an aluminum lidding foil (b) (4)

## 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 (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 name<sup>1</sup>.

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

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

#### 2.2.3 *FDA Name Simulation Studies*

110 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. Fifty-nine participants interpreted the name correctly (outpatient n=31, voice n=6, inpatient n=22). Four participants misinterpreted the capital letter 'G'; 2 for an 'L' (voice n=2) and 1 for an 'M' (outpatient n=2). Twenty-one participants misinterpreted the syllable 'Glyx' in the voice prescription study; 19 for 'Glix' and two for 'Glic'. Thirty-one participants misinterpreted the letter string 'bi'; 9 for 'bo' (inpatient n=9), 8 for 'by' (voice n=8), 3 for 'be' (voice n=3), 3 for 'bie' (voice n=3), 2 for 'ba' (inpatient n=2), 2 for 'bic' (outpatient n=2), 1 for 'bu' (outpatient n=1), 1 for 'mi' (inpatient n=1), 1 for 'so' (inpatient n=1), and

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<sup>1</sup>USAN stem search conducted on March 20, 2014.

1 for 'ta' (inpatient n=1). 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 31, 2014 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 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.

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	23
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**

Our analysis of the 23 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through E.

#### **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 29, 2014, they stated no additional concerns with the proposed proprietary name, Glyxambi.

### **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, Glyxambi, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your March 13, 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](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.<sup>2</sup>

**\*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?

<sup>2</sup> 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  $\geq 70$  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>	
<b>Y/N</b>	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	Are the lengths of the names dissimilar* when scripted?  <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	<b>Y/N</b>	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?

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"> <li>○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
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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"> <li>• Do the names begin with different first letters?</li> </ul> <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"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• 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?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>

**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. Glyxambi Study (Conducted on March 28, 2014)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Glyxambi 25mg/5mg orally once daily</i></p>	<p>Glyxambi 10 mg</p> <p>1 tablet orally once daily</p> <p>#90</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Glyxambi 10mg</i> <i>+ po qd</i> <i>#90</i></p>	

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

Study Name: Glyxambi					276 People Received Study 110 People Responded
<b>Total</b>	<b>37</b>	<b>36</b>	<b>37</b>		
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>	
GIPSAMBE	0	1	0	1	
GLADZABY	0	1	0	1	

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
GLICKSAMBI	0	1	0	1
GLICSAMBY	0	1	0	1
GLIXAMBE	0	2	0	2
GLIXAMBI	0	9	0	9
GLIXAMBIE	0	2	0	2
GLIXAMBY	0	3	0	3
GLIXSAMBI	0	2	0	2
GLIXSAMBY	0	1	0	1
GLXAMBY	0	1	0	1
GLYAXAMBI	0	0	1	1
GLYXABI	1	0	0	1
GLYXAMBA	0	0	2	2
GLYXAMBI	31	6	22	59
GLYXAMBIC	2	0	0	2
GLYXAMBIE	0	1	0	1
GLYXAMBO	0	0	9	9
GLYXAMBY	0	1	0	1
GLYXAMI	0	0	1	1
GLYXAMSO	0	0	1	1
GLYXANBU	1	0	0	1
GLYXANTA	0	0	1	1
GLYXSAMBI	0	2	0	2
LEXAMBI	0	1	0	1
LIXZEMBI	0	1	0	1
MLYXAMBI	2	0	0	2

**Appendix C: Moderately Similar Names (i.e., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with no overlap or numerical similarity in Strength and/or Dose**

No.	Proposed name: Glyxambi	POCA Score (%)
1.	Glyquin	51%

**Appendix D: 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.	Proposed name: Glyxambi Strength(s): 10 mg empagliflozin/5 mg linagliptin 25 mg empagliflozin/5 mg linagliptin Usual Dose: 1 tablet orally once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Gly-Oxide	58%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to 'oxide' when scripted or spoken.</li> </ul>
2.	Glucamide	56%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to 'camide' when scripted or spoken.</li> <li>Glyxambi has a downstroke letter, which is absent in Glucamide.</li> </ul>
3.	Glycerin	56%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to 'cerin' when scripted or spoken.</li> <li>Glyxambi has an additional upstroke letter placed at the end of the name, which is absent in Glycerin.</li> </ul>
4.	Glutamic-500	54%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to</li> </ul>

No.	<b>Proposed name:</b> Glyxambi <b>Strength(s):</b> 10 mg empagliflozin/5 mg linagliptin 25 mg empagliflozin/5 mg linagliptin <b>Usual Dose:</b> 1 tablet orally once daily	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b> <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
			'tamic' when scripted or spoken. <ul style="list-style-type: none"> <li>Glyxambi has a downstroke letter, which is absent in Glutamic-500.</li> </ul>
5.	Glauctabs	52%	<ul style="list-style-type: none"> <li>The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'bi' does not appear similar to 'tabs' when scripted or spoken.</li> <li>Glyxambi has a downstroke letter, which is absent in Glauctabs.</li> <li>In terms of phonetic differences, Glyxambi has three syllables whereas Glauctabs has two syllables.</li> </ul>
6.	Glucovance	52%	<ul style="list-style-type: none"> <li>The lengths of the names differ by two letters.</li> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to 'covance' when scripted or spoken.</li> <li>Glyxambi has a downstroke letter and two additional upstroke letters, which is absent in Glucovance.</li> </ul>
7.	Glucosamine	51%	<ul style="list-style-type: none"> <li>The lengths of the names differ by three letters.</li> <li>The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'bi' does not appear similar to 'mine' when scripted or spoken.</li> <li>Glyxambi has a downstroke letter, which is absent in Glucosamine.</li> <li>In terms of phonetic differences, Glyxambi has three syllables whereas Glucosamine has four</li> </ul>

No.	Proposed name: Glyxambi Strength(s): 10 mg empagliflozin/5 mg linagliptin 25 mg empagliflozin/5 mg linagliptin Usual Dose: 1 tablet orally once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			syllables.
8.	Glutamine	51%	<ul style="list-style-type: none"> <li>The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'bi' does not appear similar to 'mine' when scripted or spoken.</li> <li>Glyxambi has a downstroke letter, which is absent in Glutamine.</li> </ul>
9.	Glycotuss-DM	50%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'xambi' does not appear similar to 'cotuss' when scripted or spoken.</li> <li>Glycotuss-DM has an additional upstroke letter, located in the middle of the name, which is absent in Glyxambi.</li> </ul>
10.	(b) (4)	50%	<ul style="list-style-type: none"> <li>The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: (b) (4)</li> <li>(b) (4)</li> </ul>

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

No.	Name	POCA Score (%)	Failure Preventions
1.	(b) (4)	64%	(b) (4)

No.	Name	POCA Score (%)	Failure Preventions
2.	(b) (4)	60%	(b) (4)
3.	(b) (4)	58%	(b) (4)
4.	Glyoxal	57%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	(b) (4)	56%	This is a secondary proposed proprietary name. Both primary and secondary proposed names were withdrawn by the applicant (b) (4).
6.	Glytrin	54%	International product marketed in Finland, Hong Kong, Malaysia, Thailand, New Zealand, Ireland, Netherlands, Denmark, Sweden, Singapore, Portugal, UK.
7.	(b) (4)	54%	Proposed Proprietary Name found unacceptable by DMEPA ( (b) (4) ).
8.	Glucamet	53%	International product marketed in UK.
9.	Glucamine	53%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	(b) (4)	52%	Name entered by Safety Evaluator. Unable to find name in AIMS/Panorama/L:Drive (no Application #).
11.	(b) (4)	50%	Proposed Proprietary Name found unacceptable by DMEPA ( (b) (4) ). Product is considered to be on inactive status.
12.	(b) (4)	50%	This is a secondary proposed proprietary name and DMEPA found the primary proposed name unacceptable ( (b) (4) ). Product received Complete Response and NDA was not resubmitted.

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/s/  
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MISHALE P MISTRY  
05/07/2014

YELENA L MASLOV  
05/07/2014