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*****

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

Contents

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[1].

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

[1]USAN stem search conducted on March 20, 2014.

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