CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	October 28, 2010
Application Type/Number:	NDA 200678
Through:	Kristina A. Toliver, PharmD, Team Leader Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Loretta Holmes, BSN, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name:	Kombiglyze XR (Saxagliptin and Metformin HCl Extended-release) Tablets 5 mg/500 mg, 5 mg/1000 mg, and 2.5 mg/1000 mg
Applicant:	Bristol-Myers Squibb Company
OSE RCM #:	2010-387

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EXECUTIVE SUMMARY

This review summarizes DMEPA's proprietary name risk assessment of Kombiglyze XR (Saxagliptin and Metformin HCl Extended-release) Tablets, 5 mg/500 mg, 5 mg/1000 mg, and 2.5 mg/1000 mg. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Kombiglyze, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a September 29, 2010 request from Bristol-Myers Squibb Company for assessment of the proposed proprietary name, Kombiglyze XR, regarding potential name confusion with other proprietary or established drug names in the usual practice settings and promotional concerns. In addition, the Applicant submitted an independent name assessment completed by (b) (4).

1.2 REGULATORY HISTORY

DMEPA previously evaluated three proposed (b) (4) are (b) (4) (OSE Review 2010-387, dated May 27, 2010), (b) (4) (OSE Review 2010-387, dated July 13, 2010), and (b) (4). The names (b) (4) were found unacceptable by DMEPA. We had concerns with the proposed name, (b) (4) and conveyed our concerns to the Applicant in a teleconference held on September 28, 2010. The Applicant withdrew the name (b) (4) on September 29, 2010. Thus, the name Kombiglyze XR has been submitted for our evaluation.

1.3 PRODUCT INFORMATION

Kombiglyze XR is the proposed proprietary name for Saxagliptin/Metformin HCl Extended-release Tablets. It contains two antihyperglycemic agents with complementary mechanisms of action to improve glycemic control in patients with type 2 diabetes: Saxagliptin (a dipeptidyl peptidase-4 inhibitor) and Metformin Hydrochloride (a member of the biguanide class). Kombiglyze XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Saxagliptin and Metformin is appropriate.

The dose should be individualized on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended dose of Saxagliptin 5 mg and Metformin Extended-release 2000 mg. If therapy with a combination tablet containing Saxagliptin and Metformin is considered appropriate, the recommended dose of Saxagliptin is 2.5 mg or 5 mg once daily. The recommended starting dose of Metformin Extended-release is 500 mg once daily, which can be titrated to 2000 mg once daily. The maximum recommended dose of Kombiglyze XR is 5 mg/2000 mg (taken as two 2.5 mg/1000 mg tablets) once daily.

Kombiglyze XR will be supplied in the following strengths and quantities: 5 mg/500 mg and 5 mg/1000 mg (30-count, 90-count and 500-count bottles) and 2.5 mg/1000 mg (60-count and 500-count bottles). Kombiglyze XR should be stored at 20ºC to 25 ºC (68ºF to 77ºF).

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Kombiglyze XR.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'K' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Kombiglyze XR, the DMEPA Safety Evaluators also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (10 letters), upstrokes (two, lower case 'b' and 'l'), downstrokes (three, lower case 'g', 'y', and 'z'), cross strokes (none), and dotted letters (one, lower case 'i'). Additionally, several letters in Kombiglyze XR may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA Safety Evaluators also considers these alternate appearances when identifying drug names that may look similar to Kombiglyze XR.

When searching to identify potential names that may sound similar to Kombiglyze XR, the DMEPA Safety Evaluators search for names with similar number of syllables (three), stresses (KOM-bi-glyze XR, kom-BI-glyze XR, or kom-bi-GLYZE XR), and placement of vowel and consonant sounds. Additionally, the DMEPA Safety Evaluators consider that pronunciation of parts of the name can vary (see Appendix B). The Applicant's intended pronunciation of the name is "Kom-bee-glyz XR". However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

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[1] Institute for Safe Medication Practices. Confused Drug Name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

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