CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208026Orig1s000

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:	September 15, 2015
Application Type and Number:	NDA 208026
Product Name and Strength:	Jentadueto XR (linagliptin and metformin HCl extended-release) tablets, 5 mg/1000 mg and 2.5 mg/1000 mg
Product Type:	Multi-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim
Panorama #:	2015-1055053
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Jentadueto XR, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The proposed root name, 'Jentadueto', for the approved immediate release product, linagliptin and metformin HCl, was previously assessed and found acceptable in OSE Proprietary Name Review #2011-3166[1], dated November 9, 2011, under NDA 201281, which was approved on January 30, 2012.

1.2 PRODUCT INFORMATION

The following is a comparison of product characteristics for Jentadueto and Jentadueto XR. The product information for Jentadueto XR is provided in the July 27, 2015 proprietary name submission.

Table 1. Relevant Product Information for Jentadueto and Jentadueto XR

	Jentadueto (NDA 201281)	**Jentadueto XR (NDA 208026)**
Approval Date	January 30, 2012	Pending
Intended Pronunciation	JEN ta doo e'-toe	JEN ta doo e'-toe XR
Active Ingredient	Linagliptin and metformin HCl	Linagliptin and metformin HCl extended-release
Indication of Use	combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate	
Route of Administration	Oral	
Dosage Form	Tablets	
Strengths	2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	5 mg/1000 mg 2.5 mg/1000 mg
Dose & Frequency	1 tablet twice daily (max 2.5 mg linagliptin/1000 mg metformin twice daily)	1 tablet once daily (max 5 mg linagliptin and 2000 mg metformin)
How Supplied	60 & 180 count bottles	5 mg/1000 mg • 30 & 90 count bottles 2.5 mg/1000 mg

[1] Fava W. Proprietary Name Review for Jentadueto (NDA 201281). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2011 NOV 9. 29 p. OSE RCM No.: 2011-3166.

		• 60 & 180 count bottles
Storage	Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. Protect from exposure to high humidity. Store in a safe place out of reach of children.	

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[2].

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name contains two components: 1) the proposed root name, Jentadueto, and 2) the modifier XR. The Applicant indicated in their submission that the proposed root name, Jentadueto, has no derivation and the modifier 'XR' is an abbreviation for "extended release". An analysis of the proposed root name and appropriateness of the modifier is discussed in Sections 2.2.6 and 2.2.7 respectively.

2.2.3 FDA Name Simulation Studies

Sixty-nine practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. The most common misinterpretation was 'G' for the 'J'. 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, August 21, 2015 e-mail, DMEP did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[2]USAN stem search conducted on September 2, 2015.

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