CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208026Orig1s000

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	May 5, 2016
To:	Jean-Marc Guettier, MD Director **Division of Metabolism and Endocrinology Products (DMEP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Shawna Hutchins, MPH, BSN, RN Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Sharon W. Williams, MSN, BSN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Charuni Shah, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Medication Guide (MG)
Drug Name (established name):	JENTADUETO XR (linagliptin and metformin hydrochloride)
Dosage Form and Route:	extended-release tablets, for oral use
Application Type/Number:	NDA 208026
Applicant:	Boehringer Ingelheim Pharmaceuticals, Inc.

1 INTRODUCTION

On July 27, 2015, Boehringer Ingelheim Pharmaceuticals, Inc. submitted for the Agency's review a New Drug Application for JENTADUETO XR (linagliptin and metformin hydrochloride) extended-release tablets. The purpose of the submission is to seek approval for the extended release form for JENTADUETO (linagliptin and metformin hydrochloride) tablets which are currently approved.

JENTADUETO XR (linagliptin and metformin hydrochloride) extended-release tablets are used 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.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Metabolism and Endocrinology Products (DMEP) on July 31, 2015, for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG) for JENTADUETO XR (linagliptin and metformin hydrochloride) extended-release tablets.

2 MATERIAL REVIEWED

- Draft JENTADUETO XR (linagliptin and metformin hydrochloride) extended-release tablets MG received on July 27, 2015, revised by the Review Division throughout the review cycle and received by DMPP and OPDP on April 29, 2016.
- Draft, JENTADUETO XR (linagliptin and metformin hydrochloride) extended-release tablets Prescribing Information (PI) received on July 27, 2015, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on April 29, 2016.
- Approved JENTADUETO (linagliptin and metformin hydrochloride) tablet labeling dated April 28, 2015.

3 REVIEW METHODS

In 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the MG document using the Arial font, size 10.

In our collaborative review of the MG we:

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the Prescribing Information (PI)
- ensured that the MG is free of promotional language or suggested revisions to ensure that it is free of promotional language

- ensured that the MG meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the MG is consistent with the approved comparator labeling where applicable

4 CONCLUSIONS

The MG is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the MG is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the MG.

Please let us know if you have any questions.

7 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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

/s/

SHARON W WILLIAMS
05/05/2016

CHARUNI P SHAH
05/05/2016

SHAWNA L HUTCHINS
05/05/2016

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