CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210455Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: May 31, 2018

To: Myung-Joo Patricia Hong, Regulatory Project Manager
Division of Antiviral Products (DAVP)

From: Wendy Lubarsky, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sam Skariah, Team Leader, OPDP

Subject: OPDP Labeling Comments for SYMTUZA™ (darunavir, emtricitabine, and tenofovir alafenamide) tablets, for oral use

NDA: 210455

In response to DAVP consult request dated September 25, 2017, OPDP has reviewed the proposed product labeling (PI), patient package insert (PPI), and carton and container labeling for the original NDA submission for SYMTUZA™ (darunavir, emtricitabine, and tenofovir alafenamide) tablets, for oral use (Symtuza).

PI and PPI: OPDP's comments on the proposed labeling are based on the draft PI and PPI received by electronic mail from DAVP (Myung-Joo Patricia Hong) on May 17, 2018, and are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed, and comments on the proposed PPI were sent under separate cover on May 31, 2018.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling received by electronic mail from DAVP (Myung-Joo Patricia Hong) on May 30, 2018, and we have no comments at this time.

Thank you for your consult. If you have any questions, please contact Wendy Lubarsky at (240) 402-7721 or wendy.lubarsky@fda.hhs.gov .

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/s/

WENDY R LUBARSKY
05/31/2018

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 30, 2018
To:	Debra Birnkrant, MD Director **Division of Antiviral Products (DAVP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Morgan Walker, PharmD, MBA, CPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Wendy Lubarsky, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide)
Dosage Form and Route:	tablets, for oral use
Application Type/Number:	210455
Applicant:	Jassen Products, LP

1 INTRODUCTION

On September 22, 2017, Jassen Products, LP submitted for the Agency's review an original New Drug Application (NDA) 210455 for SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets. The proposed indication is for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

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 Antiviral Products (DAVP) on September 25, 2017 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets.

2 MATERIAL REVIEWED

- Draft SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets PPI received on September 22, 2017, and received by DMPP and OPDP on May 17, 2018.
- Draft SYMTUZA (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets Prescribing Information (PI) received on September 22, 2017, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on May 17, 2018.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, 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.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information

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