CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

210455Orig1s000

Trade Name:	SYMTUZA™ tablets, 800/150/200/10 mg.
Generic or Established:	darunavir, cobicistat, emtricitabine, and tenofovir alafenamide
Sponsor:	Janssen Products, LP
Approval Date:	July 7, 2018
Indication:	For the use of SYMTUZA™ (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) fixed-dose combination tablets for the treatment of HIV-1 infection in adults: • who have no prior antiretroviral treatment history; or • who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir.

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	**X**
REMS	
Officer/Employee List	**X**
Multidiscipline Review(s) • **Summary Review** • **Office Director** • **Cross Discipline Team Leader** • **Clinical** • **Non-Clinical** • **Statistical** • **Clinical Pharmacology**	**X**
Product Quality Review(s)	**X**
Clinical Microbiology / Virology Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 210455

NDA APPROVAL

Janssen Products, LP
Attention: Karen Gerry, BSc.
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Ms. Gerry:

Please refer to your New Drug Application (NDA) dated and received September 22, 2017, and your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SYMTUZA™ (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets, 800/150/200/10 mg.

This new drug application provides for the use of SYMTUZA™ (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) fixed-dose combination tablets for the treatment of HIV-1 infection in adults:

- who have no prior antiretroviral treatment history; or
- who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information and

text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed immediate container label that are identical to the immediate container label submitted on June 26, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Container Label for approved NDA 210455**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement in patients from birth to less than 3 years of age because the product would be ineffective and/or unsafe in this age group. We are waiving the pediatric study requirement in patients 3 years to less than 18 years of age weighing less than 40 kg because this fixed-dose combination does not represent a meaningful therapeutic benefit over existing therapies and is unlikely to be used in a substantial number of patients in this age group due to the small number of pediatric patients in this age group.

We are deferring submission of your pediatric study for pediatric patients weighing at least 40 kg for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the FDCA. The required study is listed below.

3430-1 Conduct your deferred pediatric trial in HIV-1 infected patients weighing at least 40 kg to assess the pharmacokinetics, safety and tolerability, and antiviral activity of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide fixed-dose combination (FDC). Study participants should be monitored for 24 weeks to

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