CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205395Orig1s000

Trade Name: PREZCOBIX

Generic Name: darunavir and cobicistat

Sponsor: **JANSSEN PRODUCTS, LP**

Approval Date: January 29, 2015

Indications: PREZCOBIX is a two drug combination of darunavir, a human immunodeficiency virus (HIV-1) protease inhibitor and cobicistat, a CYP3A inhibitor and is indicated for the treatment of HIV-1 infection in adult patients.

CENTER FOR DRUG EVALUATION AND RESEARCH

205395Orig1s000

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	**X**
REMS	
Summary Review	**X**
Officer/Employee List	**X**
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	**X**
Chemistry Review(s)	**X**
Environmental Assessment	**X**
Pharmacology Review(s)	**X**
Statistical Review(s)	
Microbiology / Virology Review(s)	**X**
Clinical Pharmacology/Biopharmaceutics Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205395Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205395

NDA APPROVAL

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

Dear Ms. Gerry:

Please refer to your New Drug Application (NDA) dated March 31, 2014 and received March 31, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Prezcobix™ (darunavir and cobicistat) tablet, 800 mg/150 mg for oral use.

We also refer to our approval letter dated January 29, 2015 which contained the following errors:

1. The Table numbers in the Prescribing Information were incorrect.

This replacement approval letter incorporates the correction of the errors. The effective approval date will remain January 29, 2015 the date of the original approval letter.

We acknowledge receipt of your amendments dated:

April 11, 2014	August 4, 2014	November 26, 2014
April 23, 2014	August 8, 2014	December 16, 2014
May 6, 2014	August 11, 2014	December 18, 2014
June 2, 2014	August 13, 2014	December 22, 2014
June 24, 2014	September 12, 2014	January 7, 2015
June 27, 2014	October 1, 2014	January 12, 2015
June 30, 2014	October 15, 2014	January 14, 2015
July 8, 2014	October 17, 2014	January 21, 2015
July 14, 2014	November 24, 2014	January 26, 2015
August 4, 2014	November 25, 2014	January 28, 2015

This new drug application provides for the use of Prezcobix™ (darunavir and cobicistat) in combination with other antiretroviral agents for treatment of HIV-1 infection.

APPROVAL & LABELING

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.

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 package insert, text for the patient information). 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.

IMMEDIATE CONTAINER LABEL

Submit the final printed immediate container label that is identical to the enclosed immediate container label, as soon as it is available, but no more than 30 days after it is printed. Please submit the label electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Container Label for approved NDA 205395**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Nina Mani
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6317
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.