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APPLICATION NUMBER:

209512Orig1s000

NON-CLINICAL REVIEW(S)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

PHARMACOLOGY/TOXICOLOGY NDA/BLA REVIEW AND EVALUATION

Application number: 209512
Supporting document: 000
Applicant's letter date: December 7, 2016
CDER stamp date: December 7, 2016
Product: Norvir (ritonavir), powder for suspension
Indication: Treatment of HIV-1 infection
Applicant: AbbVie, Inc.

Review Division: DAVP
Reviewer: Pritam Verma, Ph.D.
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1 Executive Summary

1.1 Introduction

AbbVie Inc. has submitted a New Drug Application to request approval of the use of Norvir (ritonavir) Powder for Oral Suspension for the treatment of patients with HIV infection. Norvir Oral Solution (80 mg ritonavir/mL) was approved under NDA 020659. AbbVie has now developed an alternate formulation of ritonavir for the pediatric population which does not contain ethanol or propylene glycol and has an improved shelf life. (b) (4)

This NDA is supported by the safety and efficacy information included in the following NDAs: Norvir Capsules (020945), Oral Solution (020659), and Tablets NDA (022417). A comprehensive review of the nonclinical studies for NORVIR has been performed under the above mentioned NDAs.

1.2 Recommendations

1.3.1 Approvability

It is recommended that NORVIR powder proposed changes be approved.

1.3.2 Additional Non Clinical Recommendations

No additional nonclinical studies are recommended.

1.3.3 Labeling

The final nonclinical label updates are reflected in the final approved label.

Drug Information

2.1 Drug:

NORVIR Powder for oral suspension

2.2 Relevant INDs, NDAs and DMFs

NDAs 20659, 020945 and 022417

2.3 Drug Formulation

Beige/pale yellow to yellow powder in child-resistant packet. Each packet contains 100 mg of ritonavir.

2.4 Comments on Novel Excipients

N/A.

2.5 Comments on Impurities/Degradants of Concern

N/A

2.6 Proposed Clinical Population and Dosing Regimen

The recommended dosage of ritonavir is 600 mg twice daily by mouth to be taken with meals. Use of a dose titration schedule may help to reduce treatment-emergent adverse events while maintaining appropriate ritonavir plasma levels. Ritonavir should be started at no less than 300 mg twice daily and increased at 2 to 3 day intervals by 100 mg twice daily. The maximum dose of 600 mg twice daily should not be exceeded upon completion of the titration.

2.7 Regulatory Background

NORVIR is an approved drug product under NDAs 20659, 020945 and 022417

3. Studies Submitted

No nonclinical studies were submitted. No additional nonclinical studies are recommended. A comprehensive review of the nonclinical studies for NORVIR has been performed under NDAs 20659, 020945 and 022417.

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/s/

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05/01/2017

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05/01/2017