CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204311Orig1s000

NON-CLINICAL REVIEW(S)

Memo to the Division File

NDA 204311 (SN-41) Abacavir and Lamivudine (60 mg / 30 mg) Tablets for Oral Suspension

From: Zheng Li, Ph.D., DABT, Pharmacology/Toxicology reviewer

Through: Peyton Myers, Ph.D., DABT, Pharmacology/Toxicology supervisor

To: Monica Zeballos, PharmD

Subject: Pharmacology/Toxicology review

Date: 12/08/2023

Regulatory Background:

In combination with other antiretroviral agents, Abacavir and Lamivudine (60 mg / 30 mg) Tablets for Oral Suspension is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in pediatric patients aged 3 months and older or weighing at least 5 kg. The proposed drug is a 505 (b)(2) product, with Ziagen®Oral Solution/Epivir®Oral Solution (020978/020596) as the listed drug products that are the basis for the submission.

On October 19, 2023, the Agency sent an Information Request on (b) (4) Mylan Laboratories Limited (MLL), a Viatris Company, submitted full response to the Agency's comments.

(b) (4)

Because no (b) (4) and any other new impurity are detected, from Pharmacology / Toxicology perspective, we have minimal concerns regarding the safety of the drug product and agree to approve this NDA.

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/s/

ZHENG LI
12/13/2023 03:48:20 PM

LAINE P MYERS
12/13/2023 05:18:43 PM