DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022141/S-024

SUPPLEMENT APPROVAL

Mylan Pharmaceuticals Inc
US Agent for: Mylan Laboratories Limited
Attention: Robert Barto
Senior Director, Regulatory Affairs Officer
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26505-4310

Dear Mr. Barto:

Please refer to your Supplemental New Drug Application (sNDA) dated March 22, 2018, received March 22, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CIMDUO® (Lamivudine and Tenofovir Disoproxil Fumarate) Tablets, 300 mg/300 mg.

We also refer to our approval letter dated June 19, 2018, which contained the following error: The statement "We also refer to the supporting amendment received on May 29, 2018. This sNDA, as amended, was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR)". This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 19, 2018, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for the following change:

- Revision to the analytical method (b) (4) for dissolution testing of the drug product

APPROVAL

We have completed our review of this supplemental new drug application as amended. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Omolara Laiyemo, PharmD, Regulatory Business Process Manager, at (240) 402 - 3842 or via email at Omolara.Laiyemo@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
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