NDA 215596/S-001

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals USA, Inc.
Attention: Michael A. Cronin, PharmD
Director, Global Regulatory Affairs
650 East Kendall Street
Cambridge, MA 02142

Dear Dr. Cronin:

Please refer to your supplemental new drug application (sNDA) dated and received on November 24 ,2021 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Livtencity (maribavir) oral tablets.

This "Changes Being Effected" sNDA provides for changes to correct an error in the dosage instructions on the carton label . See table below:

Initial Approved Carton (23 November 2021)	Corrected Final Carton (24 November 2021)
"Dosage: 200 mg twice a day. See enclosed Full Prescribing Information for detailed dosing instructions."	"Dosage: 400 mg (two 200 mg tablets) twice a day. See enclosed Full Prescribing Information for detailed dosing instructions."

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.

CARTON LABELING

Submit final printed carton labeling that are identical to the enclosed carton submitted on November 24, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 215596/S-001**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Alicia Moruf, PharmD, MPH, RAC-US, Regulatory Project Manager, at 301-796-3953.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
01/18/2022 04:00:24 PM
on behalf of Division Director