

EUA 122

**EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS**

Invivyd, Inc.
Attention: Timothy Kachmar, MS
Regulatory Affairs
1601 Trapelo Road, Suite 178
Waltham, MA 02451

Dear Timothy Kachmar:

Please refer to your Emergency Use Authorization (EUA) for pemivibart for pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40kg):

- who are not currently infected with SARS-CoV-2 and who have not been known to be exposed to someone who is infected with SARS-CoV-2 and,
- who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate response to COVID-19 vaccination,

issued on March 22, 2024, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer to your September 4, 2024, submission of updated neutralization activity data against recently and currently circulating SARS-CoV-2 variants including JN.1.50, KP.3.1.1, and LB.1. We also refer to your September 10 and September 25, 2024, submissions which incorporate these changes.

We have reviewed your submissions and have updated the EUA Fact Sheet for Healthcare Providers accordingly.

The updated Fact Sheet for Healthcare Providers is attached to this correspondence for your reference with September 2024, as the new revised date.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the August 26, 2024, 2024¹, letter authorizing the emergency use of pemivibart for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents.

¹ The EUA for pemivibart was issued initially on March 22, 2024. The Letter of Authorization was subsequently reissued on April 3, 2024 and August 26, 2024.

Sincerely,

{See appended electronic signature page}

Wendy Carter, DO
Acting Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- EUA Fact Sheet
 - Fact Sheet for Health Care Providers

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/s/

WENDY W CARTER
09/26/2024 09:29:40 AM