



EUA 122

**EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS**

Invivyd, Inc.
Attention: Barry Sickels, PhD
Senior Vice President, Regulatory Affairs
1601 Trapelo Road, Suite 178
Waltham, MA 02451

Dear Dr. Sickels:

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 April 23, 2024 submission of updated JN.1.11.1 pseudotyped virus-like particle data followed by your April 25, 2024 and May 7, 2024 submissions, proposing the following changes to the Fact Sheet for Health Care Providers (HCPs):

- Addition of JN.1.11.1 pseudotyped virus-like particle data
- Updated the nomenclature for RBD substitution V483- for consistency with CoV-Spectrum
- Corrected typographical error for the spike sequence substitution at position 498, replacing the previously stated 489.
- Spike substitution amino acid order was corrected to R498Q, Y501N, and H505Y to reflect the changes relative to XBB.1.5.6 at these positions.

We have reviewed your submissions and agree with the proposed changes as described above.

The updated Fact Sheet for Health Care Providers is attached to this correspondence for your reference with May 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 March 22, 2024¹, letter authorizing the emergency use of pemivibart for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents.

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

¹ The EUA for pemivibart was issued on March 22, 2024.