



April 25, 2022

Gilead Sciences, Inc.
Attention: Madelyn Low, MBS
Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

RE: Emergency Use Authorization 046

Dear Ms. Low:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA 046) for emergency use of Gilead Sciences, Inc.'s ("Gilead") Veklury (remdesivir), issued initially on May 1, 2020, and amended on August 28, 2020, October 1, 2020, October 16, 2020, October 22, 2020, and January 21, 2022.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved¹, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

On April 25, 2022, the Agency approved a supplemental New Drug Application (NDA) to NDA 214787, which expanded the approved indication to the following:

Veklury is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are:

- *Hospitalized, or*
- *Not Hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.*

Based on this approval, FDA has concluded that NDA 214787 for Veklury is an adequate, approved¹, and available alternative to Veklury available for emergency use, for the treatment of COVID-19 for purposes of section 564(c)(3) of the Act.

Accordingly, FDA revokes EUA 046 for emergency use of Veklury, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Veklury that was authorized by FDA for emergency use under EUA 046 is no longer authorized by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

¹ In the context of section 564, the term “approved” refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.