Sponsor	Assistant Secretary for Preparedness and Response (ASPR)
Product Name	COVID-19 convalescent plasma.
Indication	treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting
Original CBER Receipt Date of EUA Withdrawal Request (if sponsor requested withdrawal)	August 13, 2025

On February 4, 2020, as amended on March 15, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or that has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, and pursuant to Section 564 of the Act, on March 27, 2020, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of any authorization issued under Section 564(a) of the Act.

On August 23, 2020, FDA issued an Emergency Use Authorization (EUA) for emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. This EUA was subsequently reissued with revisions three times. Most recently on December 28, 2021, the EUA was revised to, among other things, limit the authorization to the use of COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting.

FDA has determined that circumstances make revocation of the EUA for COVID-19 convalescent plasma appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). On August 13, 2025, FDA received a request for its withdrawal. In addition, as of December 10, 2024, there is now licensed convalescent plasma for the use that is described in the EUA. Specifically, on December 10, 2024, FDA approved a supplemental Biologics License Application (sBLA) for COVID-19 Convalescent Plasma with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19 in patients with

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020. U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)*. March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

immunosuppressive disease or receiving immunosuppressive treatment. Further, FDA is aware that current use of COVID-19 convalescent plasma under the EUA is limited to a small number of patients and that the supply of licensed COVID-19 convalescent plasma is expected to meet clinical need. Due to all of these circumstances, we have determined that circumstances exist that make it appropriate to revoke the EUA and doing so is appropriate to protect the public health or safety.

In the July 2024 guidance document "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma," FDA provides recommendations to blood establishments for the submission of a Biologics License Application (BLA) for the manufacture of COVID-19 convalescent plasma for transfusion intended to treat patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-investigational-and-licensed-covid-19-convalescent-plasma). The guidance also provides FDA's recommendations for Investigational New Drug applications (INDs) for investigational COVID-19 convalescent plasma for transfusion.

FDA does not intend to object to the use of any remaining inventory of the COVID-19 convalescent plasma that was distributed prior to revocation of the EUA.[2] The 2024 guidance document "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma" addresses FDA's recommendations with respect to the use of any remaining inventory of COVID-19 convalescent plasma that was distributed prior to revocation of the EUA.

Accordingly, pursuant to section 564(g)(2) of the FD&C Act, I recommend revoking EUA 26382 for COVID-19 convalescent plasma, effective the date the FDA revocation letter is signed. There are no open amendments associated with this EUA at the time of this revocation request.

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

Signature: _____
Center Director
Vinayak Prasad, M.D., M.P.H.

[2] See FDA's guidance document, "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma" (July 2024, available at: https://www.fda.gov/media/180209/download).