Our Reference: EUA 26382

EMERGENCY USE AUTHORIZATION
REVOKED
August 27, 2025

Assistant Secretary for Preparedness and Response
Attention: John Knox
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Knox:

This letter is in response to the request from the Assistant Secretary for Preparedness and Response (ASPR), received August 13, 2025, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for COVID-19 convalescent plasma. This EUA was initially issued on August 23, 2020.

The authorization of a biological product 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 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 circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). FDA has determined that circumstances make revocation of this authorization appropriate to protect the public health or safety.

In determining that there are circumstances that make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act), we considered several factors. We understand that you have requested that the EUA for COVID-19 convalescent plasma be revoked. In addition, as of December 10, 2024, there is now licensed convalescent plasma for the use that is described in your 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 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 your EUA and doing so is appropriate to protect the public health or safety.

Accordingly, FDA revokes EUA 26382 for emergency use of COVID-19 convalescent plasma pursuant to section 564(g)(2) of the Act. As of the date of this letter, COVID-19 convalescent plasma which was authorized by FDA for emergency use under EUA 26382, is no longer authorized by FDA.

FDA does not intend to object to the use of any remaining inventory of the COVID-19 convalescent plasma that was distributed before revocation of the EUA.[1] The Guidance for Industry, *Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma,* July 2024,[2] 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.

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

Sincerely,

Vinayak Prasad, M.D., M.P.H
Director
Center for Biologics Evaluation and Research

[1] See *Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma* Guidance for Industry, July 2024 (https://www.fda.gov/media/180209/download).

[2] The guidance also provides FDA's recommendations to blood establishments for the submission of a Biologics License Application for the manufacture of COVID-19 convalescent plasma.