Page 2 – EUA 28237 – Ms. Callahan

letter, the Novavax COVID-19 Vaccine, Adjuvanted, which was authorized by FDA for emergency use under EUA 28237, 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,

VINAYAK K. PRASAD -S

Digitally signed by VINAYAK K. PRASAD -S
Date: 2025.08.27 10:45:56 -04'00'

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–19272 Filed 10–1–25; 8:45am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2305]

Revocation of Emergency Use of a Biological Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (ASPR/HHS) for COVID–19 convalescent plasma. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of August 27, 2025.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The revocation may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010 or emailing *industry.biologics@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On August 23, 2020, FDA issued an EUA to ASPR/HHS for COVID–19 convalescent plasma, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on February 19, 2021 (86 FR 10290), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website.

The authorization of a biological product for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on August 13, 2025, ASPR/HHS requested revocation of the Authorization of COVID–19 convalescent plasma. On August 27, 2025, FDA revoked the Authorization. In determining that there are circumstances that make revocation of this EUA appropriate to protect the public health or safety, FDA also considered that, as of December 10, 2024, there is licensed COVID–19 convalescent plasma for the same use that is described in the EUA, 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, FDA has determined that revoking this EUA is appropriate to protect the public health or safety.

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for COVID–19 convalescent plasma. The revocation in its entirety follows and provides explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the Authorization and revocation are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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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 K. PRASAD -S

Digitally signed by VINAYAK K. PRASAD -S
Date: 2025.08.27 10:38:12 -04'00'

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–19270 Filed 10–1–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No: FDA–2025–N–3774]

Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the Committee is to provide advice and recommendations to FDA on pediatric regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.