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https://federalregister.gov/d/2025-19272, and on **https://govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-3792]

Revocation of Emergency Use of Three Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUA) (the Authorizations) issued to Pfizer, Inc. for Pfizer-BioNTech COVID-19 Vaccine; to ModernaTX, Inc. for Moderna COVID-19 Vaccine; and to Novavax, Inc. for Novavax COVID-19 Vaccine, Adjuvanted. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorizations for Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Novavax COVID-19 Vaccine, Adjuvanted are revoked as of August 27, 2025.

ADDRESSES: Submit written requests for single copies of the revocations 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 revocations 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 revocations.

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 December 11, 2020, FDA issued an EUA to Pfizer, Inc. for Pfizer-BioNTech COVID-19 Vaccine, subject to the terms of the Authorization. On December 18, 2020, FDA issued an EUA to ModernaTX, Inc. for Moderna COVID-19 Vaccine, subject to the terms of the Authorization. Notice of the issuance of these two Authorizations were published in the *Federal Register* on January 19, 2021 (86 FR 5200), as required by section 564(h)(1) of the FD&C Act. On July 13, 2022, FDA issued an EUA to Novavax, Inc. for Novavax COVID-19 Vaccine, Adjuvanted, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on August 29, 2022 (87 FR 52790), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to these three Authorizations 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 Criteria Met

On August 27, 2025, FDA revoked the EUAs for Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Novavax COVID-19 Vaccine, Adjuvanted, because FDA determined that it is appropriate, for the reasons discussed below, to revoke these Authorizations under section 564(g)(2)(C) of the FD&C Act.

As more thoroughly explained in the full revocation letters, circumstances exist that make revocation of each of the EUAs appropriate to protect the public health or safety. For example,

there are now approved COVID-19 vaccines for use in certain individuals that were included in the target age groups of each of these EUAs. Specifically, there are approved COVID-19 vaccines for use in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. In addition, widespread natural and vaccine-acquired immunity has reduced severe outcomes, hospitalizations, and deaths from COVID-19. While safety concerns were not the basis for FDA's decision to revoke the EUAs, due to various considerations, FDA determined that circumstances exist that make revocation of the EUAs appropriate to protect the public health or safety.

III. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs for Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Novavax COVID-19 Vaccine, Adjuvanted. The revocations in their entireties follow and provide explanations 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 Authorizations and revocations are available on the internet at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27034

EMERGENCY USE AUTHORIZATION REVOKED
August 27, 2025

BioNTech Manufacturing GmbH
Attention: Leslie Sands
Pfizer, Inc.
66 Hudson Boulevard East
New York, NY 10001

Dear Ms. Sands:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) 27034 for the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19. This EUA was initially issued on December 11, 2020, for individuals 16 years of age and older and was amended and reissued in its entirety by FDA multiple times, most recently on August 22, 2024, to, among other things, authorize the use of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) for use in individuals 6 months through 11 years of age.

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 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 when 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 such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). As of July 9, 2025, there is now an approved vaccine for use in certain individuals in the age group that is the target of your EUA. Specifically, on July 9, 2025, FDA approved Spikevax (COVID-19 Vaccine, mRNA) (2024-2025 Formula) for use in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. In addition, on August 27, 2025, FDA approved Comirnaty (COVID-19 Vaccine, mRNA) (2025-2026 Formula) for use in individuals who are 65 years of age and older, or 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. Prior to July 9. 2025, the only COVID-19 vaccines that were available for use in individuals 6 months through 11 years of age were authorized under EUA. Furthermore, widespread natural and vaccine-acquired immunity has reduced severe outcomes, hospitalizations, and deaths from COVID-19. While safety concerns are not the basis for our decision to revoke the EUA, due to all of these circumstances, I 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 27034 for emergency use of the Pfizer-BioNTech COVID-19 Vaccine pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Pfizer-BioNTech COVID-19 Vaccine, which was authorized by FDA for emergency use under EUA 27034, 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

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Date: 2025.08.27 10:46:46 -04'00'

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

U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27073

EMERGENCY USE AUTHORIZATION REVOKED
August 27, 2025

ModernaTX Inc.
Attention: Mr. Brady Nesbitt
325 Binney Street
Cambridge, MA 02142

Dear Mr. Nesbitt:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) 27073 for the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19. This EUA was initially issued on December 18, 2020, for individuals 18 years of age and older and was amended and reissued in its entirety by FDA multiple times, most recently on August 22, 2024, to, among other things, authorize the use of Moderna COVID-19 Vaccine (2024-2025 Formula) for use in individuals 6 months through 11 years of age.

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 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 when 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 such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). We acknowledge your July 24, 2025, amendment to the EUA in which you state that all manufacturing operations under the EUA have ceased and that you will stop distribution of Moderna COVID-19 Vaccine (2024-2025 Formula) after approval of Spikevax (COVID-19 Vaccine, mRNA) (2025-2026 Formula). We also note that on August 27, 2025, Spikevax (COVID-19 Vaccine, mRNA) (2025-2026 Formula) was approved for use in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. Additionally, since July 9, 2025, there has been an approved COVID-19 vaccine for use in certain individuals in the age group that is the target of your EUA. Specifically, on July 9, 2025, FDA approved Spikevax (COVID-19 Vaccine, mRNA) (2024-2025 Formula) for use in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe

outcomes from COVID-19. Prior to July 9, 2025, the only COVID-19 vaccines that were available for use in individuals 6 months through 11 years of age were authorized under EUA. In addition, widespread natural and vaccine-acquired immunity has reduced severe outcomes, hospitalizations, and deaths from COVID-19. While safety concerns are not the basis for our decision to revoke the EUA, due to all of these considerations, I 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 27073 for emergency use of Moderna COVID-19 Vaccine pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Moderna COVID-19 Vaccine, which was authorized by FDA for emergency use under EUA 27073, 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

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Date: 2025.08.27 10:45:04 -04'00'

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

Our Reference: EUA 28237

EMERGENCY USE AUTHORIZATION REVOKED
August 27, 2025

Novavax, Inc.
Attention: Ms. Kathleen Callahan
700 Quince Orchard Road
Gaithersburg, MD 20878

Dear Ms. Callahan:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) 28237 for the emergency use of Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19. This EUA was initially issued on July 13, 2022, for individuals 18 years of age and older and was amended and reissued in its entirety by FDA multiple times, most recently on August 30, 2024, to, among other things, authorize the use of Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) for use in individuals 12 years of age and older.

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 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 when 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 such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). We are not aware of any plans you have to distribute vaccine under the EUA. There are approved COVID-19 vaccines for use in certain individuals in the age group that is the target of your EUA, Specifically, there are approved COVID-19 vaccines for use in individuals who are 65 years of age and older, or 12 through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. In addition, widespread natural and vaccine-acquired immunity has reduced severe outcomes, hospitalizations, and deaths from COVID-19. While safety concerns are not the basis for our decision to revoke the EUA, due to all of these considerations, I 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 28237 for emergency use of Novavax COVID-19 Vaccine, Adjuvanted pursuant to section 564(g)(2) of the Act. As of the date of this

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

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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: 10/1/2025 8:45 am; Publication Date: 10/2/2025]