T 859.04: EUA Revocation Memo Template

EUA Number	27034
Sponsor	Pfizer, Inc.
Product Name	Pfizer-BioNTech COVID-19 vaccine
Authorized Use	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.
Original CBER Receipt Date of EUA Withdrawal Request (if sponsor requested withdrawal)	N/A

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 of the Act.

On December 11, 2020, FDA issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older. This EUA was reissued multiple times, most recently on August 22, 2024, to, among other things, authorize the use of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) 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).

[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").

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 COVID-19 vaccine for use in certain individuals in the age group that is the target of the 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. The circumstances of COVID-19 are also not what they previously were. The risk of severe outcomes from COVID-19 has decreased dramatically over the last four years.[2] Hospitalizations from COVID-19 have declined between 2021 and 2025.[3] The infection fatality rate is estimated to have decreased approximately 10-fold with the emergence of the newer variants of SARS-CoV-2.[4] Furthermore, naturally acquired immunity from SARS-CoV-2 infection(s) that prevents severe COVID-19 appears robust.[5]

On July 28, 2025, Pfizer conveyed the below concerns to us. Pfizer identified three considerations to support the proposition that EUA revocation is not in the public interest. First, Pfizer stated that there is a risk of a gap in the vaccination series due to inadequate guidance to practitioners for children with an incomplete vaccination series initiated with the multi-dose series for the Pfizer-BioNTech COVID-19 Vaccine. Specifically, Pfizer stated that by withdrawing the EUA, providers and caregivers may incorrectly infer that the withdrawal is the result of undisclosed safety concerns. The company stated that maintaining the EUA will continue to protect the public health and safety of this population, whereas rescinding it could jeopardize public health and safety. Pfizer also stated that the approved Spikevax labeling only provides guidance for children 6 through 23 months of age based on prior receipt of Moderna COVID-19 vaccines, and does not address children who began their series with the Pfizer-BioNTech COVID-19

[2] Riedmann U, Chalupka A, Richter L, Sprenger M, Rauch W, Krause R, Willeit P, Schennach H, Benka B, Werber D, Høeg TB, Ioannidis JP, Pilz S. COVID-19 case fatality rate and infection fatality rate from 2020 to 2023: Nationwide analysis in Austria. J Infect Public Health. 2025 Apr;18(4):102698.

[33] Thornburg, N. 2024-2025 Update on Current Epidemiology of COVID-19 and SARS-CoV-2 Genomics. CDC May 2025 https://www.fda.gov/media/186593/download.

[4] Riedmann U, Chalupka A, Richter L, Sprenger M, Rauch W, Krause R, Willeit P, Schennach H, Benka B, Werber D, Høeg TB, Ioannidis JP, Pilz S. COVID-19 case fatality rate and infection fatality rate from 2020 to 2023: Nationwide analysis in Austria. J Infect Public Health. 2025 Apr;18(4):102698.

[5] Prasad, V., Makaray, M.A., An evidence-based approach to COVID-19 vaccination. NEJM. 2025 June; 392(24): 2484.

vaccines. Pfizer stated that the lack of clear guidance, combined with schedule disruption, may reduce protection against COVID-19 and further increase the risk of severe COVID-19 among children.

FDA has considered this argument but disagrees that there is inadequate guidance for individuals who started the vaccination series with a Pfizer-BioNTech COVID-19 Vaccine. CDC publishes clinical considerations that address exactly these types of scenarios. For example, the current version of the clinical considerations document addresses when an age-appropriate vaccine from a different manufacturer may be administered [Ref: Administration of COVID-19 vaccine doses from different manufacturers]. Healthcare providers can access this guidance via the CDC's website. CDC can also update the guidance as needed to specifically address the revocation of the Pfizer-BioNTech COVID-19 Vaccine EUA. Accordingly, FDA disagrees that this first consideration is a basis for keeping the EUA in place.

Second, Pfizer states that there is risk of supply interruption in children 6 months through 11 years of age. Pfizer states that having more than one manufacturer able to provide COVID-19 vaccines for this age group is an important part of maintaining supply chain resilience. FDA has considered this argument. FDA agrees that with the revocation of the Pfizer-BioNTech COVID-19 Vaccine EUA, there will, at that time, only be one licensed COVID-19 vaccine approved for use in individuals 6 months through 4 years of age.[6] However, Pfizer has not identified any evidence showing that the manufacturer of the currently-approved COVID-19 vaccine for this age group is unable to supply the relevant population and FDA does not agree that this consideration is sufficient reason to keep the Pfizer-BioNTech COVID-19 Vaccine EUA in place. Accordingly, FDA disagrees that this second consideration is a basis for keeping the EUA in place.

Third, Pfizer states that revoking the EUA would eliminate an important COVID-19 vaccine option with a vaccine that contains lower doses of mRNA. Pfizer states that revoking the EUA would eliminate a parent's choice for their child to receive lower overall dose levels of an mRNA COVID-19 vaccine. FDA has considered this argument but disagrees with its premise. Pfizer has not presented any comparative evidence to demonstrate a more favorable or even a noninferior benefit-risk between its vaccine and the COVID-19 vaccine that is approved for use for the relevant population. FDA is not aware of any data demonstrating that the lower quantity of mRNA in the Pfizer-BioNTech COVID-19 Vaccine is preferable to the quantity of mRNA in the approved COVID-19

[6] At the time of the EUA revocation, a Pfizer-BioNTech BLA supplement has been approved to license Comirnaty for use in individuals 65 years of age and older, and 5 through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. FDA also anticipates that Spikevax will continue to be licensed for use in individuals 65 years of age and older, and 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. Accordingly, the 6 month through 4 years is the only age cohort for whom FDA anticipates there will be only one COVID-19 vaccine with marketing authorization .

Vaccine for this age group. Accordingly, FDA disagrees that this third consideration is a basis for keeping the EUA in place.

We have evaluated the three considerations that Pfizer identified as supporting the proposition that EUA revocation is not in the public interest. For the above reasons, Pfizer's arguments regarding the public interest are not persuasive.

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 EUA 27034 and doing so is appropriate to protect the public health or safety.

Accordingly, pursuant to section 564(g)(2) of the FD&C Act, I recommend revoking EUA 27034 for emergency use of the Pfizer-BioNTech COVID-19 Vaccine, effective the date the FDA revocation letter is signed. There are 9 open amendments, at the time of this memo. These 9 amendments will be closed as withdrawn as a result of the EUA revocation.

FDA provided notice of the agency's intent to revoke the EUA on July 11, 2025, and this decision is consistent with the notice we provided. Notice of this revocation will also 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.