T 859.04: EUA Revocation Memo Template

EUA Number	27073
Sponsor	ModernaTX Inc.
Product Name	Moderna 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 18, 2020, FDA issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 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 Moderna 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

[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").

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). In EUA amendment 738 Moderna TX Inc. confirmed that all manufacturing operations under the EUA have ceased and that they will stop distributing Moderna COVID-19 Vaccine (2024-2025 Formula) under the EUA after the approval of Spikevax (COVID-19 Vaccine, mRNA) (2025-2026 Formula). 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 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. Previously, the only COVID-19 vaccines that were available for individuals 6 months through 11 years of age were authorized under EUA. In addition, the circumstances of COVID-19 are 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 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] 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 27073 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 27073 for emergency use of the Moderna COVID-19 Vaccine, effective the date the FDA revocation letter is signed. There are no open amendments associated with this EUA at the time of this revocation.

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[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.

[3] 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.

FDA also notes that Moderna TX has stated that following approval of Spikevax (COVID-19 Vaccine, mRNA) (2025–2026 Formula), any remaining Moderna COVID-19 Vaccine (2024–2025 Formula) manufactured under EUA will be discarded in accordance with established internal procedures and that customers may return any unused Moderna COVID-19 Vaccine (2024-2025 Formula) to Moderna in accordance with current processes.

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.