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