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