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