



Our Reference: EUA 27073

October 13, 2023

ModernaTX Inc.
Attention: Dr. Michelle Olsen
200 Technology Square
Cambridge, MA 02139

Re: EUA 27073 - Emergency Use Authorization of Moderna COVID-19 Vaccine, Reissued on September 11, 2023, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Request in Amendment received on October 13, 2023, to Update the Authorized Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) -

Dear Ms. Olsen:

This letter is to notify you that we have granted the following change to your Authorized Fact Sheets as required by the Food and Drug Administration (FDA).

We concur with removing the phrase “enrolled in the federal COVID-19 Vaccination Program” from the first sentence of the highlights section in the EUA Fact Sheets for Healthcare Providers Administering Vaccine. This EUA Fact Sheet has also been updated to include other minor editorial changes.

By submitting this amendment for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the September 11, 2023 letter authorizing the emergency use of Moderna COVID-19 Vaccine.

Sincerely,

David Kaslow, M.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research