Our Reference: EUA 27073

November 1, 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 November 1, 2023, to Update the Authorized Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) -

Dear Dr. Olsen:

This letter is to notify you that we have granted the following changes to your Authorized Fact Sheet For Healthcare Providers Administering Vaccine as required by the Food and Drug Administration (FDA):

2.1 Preparation for Administration

- Withdraw a single 0.25 mL dose using a sterile needle and syringe.
- Discard the vial and excess volume after extracting a single dose.
- Addition of a graphic depicting the withdrawal of a 0.25 mL dose from the vial using a graduated syringe.

2.2 Administration

- Administer the 0.25 mL dose of Moderna COVID-19 Vaccine intramuscularly.

11. Description
The description of a single dose vial with a dark blue cap and a label with a green box was removed.

16. How Supplied/Storage and Handling
Content of the vial expressed in mL was removed.

The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) 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 C. Kaslow, M.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

U.S. Food & Drug Administration
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