



December 9, 2021

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

**Re:** EUA 27073/308 - Emergency Use Authorization of Moderna COVID-19 Vaccine, Reissued on November 19, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);  
December 7, 2021 Submission to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information), and the Authorized Fact Sheet for Recipients and Caregivers as requested by FDA.

Dear Dr. Olsen:

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

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Full Prescribing Information) to include the following new information.

### **2.3 DOSING AND SCHEDULE**

#### **Booster Dose**

This section was clarified to specify that the age range eligible for a single heterologous booster dose of the Moderna COVID-19 Vaccine (0.25 mL) is individuals 18 years of age and older.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency. The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has also been updated to include other minor editorial changes.

In addition, the EUA Fact Sheet for Recipients and Caregivers has been revised to include the following new information:

### **HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**

#### **Booster Dose**

This section was clarified to specify that the age range eligible for a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) is individuals 18 years of age and older.

With this submission to FDA, you have complied with the Conditions of Authorization stated in the November 19, 2021, letter re-authorizing the emergency use of Moderna COVID-19 Vaccine.

Sincerely,

Peter Marks, MD, PhD  
Acting Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research