DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

August 30, 2021

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 August 12, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Amendment submitted August 27, 2021, 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

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.

5 WARNINGS AND PRECAUTIONS

5.2 Myocarditis and Pericarditis

This section was modified to read: "Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html)".

'**5.3 Syncope**' Section was added and includes the following information:

"Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting."

6. OVERALL SAFETY SUMMARY

6.2 Post-Authorization Experience

"Nervous System Disorders: Syncope" was added as an adverse reaction identified during post-authorization use of the Moderna COVID-19 Vaccine.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency. In addition, the following Section was modified as follows:

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2.

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 remove from several sections the statement that there is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19 and to include the following new information under the Section:

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine.

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

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?
Tell your vaccination provider about all of your medical conditions, including if you:

- have ever fainted in association with an injection.

By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the August 12, 2021, letter re-authorizing the emergency use of Moderna COVID-19 Vaccine.

Sincerely,

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Marion Gruber, PhD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research