DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

June 25, 2021

ModernaTX Inc.
Attention: Dr. Carla Vinals
200 Technology Square
Cambridge, MA 02139

**Re:** EUA 27073/201 - Emergency Use Authorization of Moderna COVID-19 Vaccine, Reissued on February 25, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Amendments submitted June 24 and June 25, 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. Vinals:

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 PRECUATIONS**

5.2 Myocarditis and Pericarditis

- Reports of adverse events following use of the Moderna COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. Typically, onset of symptoms has been within a few days following receipt of the Moderna COVID-19 Vaccine. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms, but information is not yet available about potential long-term sequelae. The decision to administer the Moderna COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. The CDC has published clinical considerations relevant to myocarditis and pericarditis associated with administration of the Moderna COVID-19 Vaccine (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

**6. OVERALL SAFETY SUMMARY**

- Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

**6.2 Post Authorization Experience**

- The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.
  - Cardiac Disorders: myocarditis, pericarditis
  - Immune System Disorders: anaphylaxis

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:

**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 had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)

**WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?**

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine:
  - Chest pain
  - Shortness of breath
  - Feelings of having a fast-beating, fluttering, or pounding heart.

- Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:
  - Myocarditis (inflammation of the heart muscle)
  - Pericarditis (inflammation of the lining outside the heart)

By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the February 25, 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