DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

April 1, 2021

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

Re: EUA 27073 - Emergency Use Authorization of Moderna COVID 19 Vaccine, Issued on February 25, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Requests for multiple Amendments dated January 14, 2021 - April 1, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), the Authorized Fact Sheet for Recipients and Caregivers, and the Carton and Vial Labels;
Requests for multiple Amendments dated January 14, 2021 - April 1, 2021 to Authorize an Additional Multi-Dose Vial Containing a Maximum of 15 Doses and Related Chemistry Manufacturing and Control Changes.

Dear Dr. Vinals:

This letter is to notify you that we have reviewed the requested changes and data to support the revisions to your Authorized Fact Sheets and the Carton and Vial Labels and your requests to authorize an additional multi-dose vial presentation containing a maximum of 15 doses and related Chemistry Manufacturing and Control Changes.

We concur with the related updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following changes and clarifications. These changes also include revisions requested by FDA:

Storage and Handling:

- During storage, minimize exposure to room light.
- Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).
- Vials should be discarded 12 hours after the first puncture.
- Thawed vials can be handled in room light conditions.
- If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized.
- Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

Dose Preparation:

- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- The Moderna COVID-19 Vaccine is provided in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial and more than 13 doses from the maximum of 15 doses vial.
- Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.

Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors:

- The title of this section was revised.

Adverse Reactions/Overall Safety Summary:

- Severe allergic reactions, including anaphylaxis, have been reported following the administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.
- Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.
- Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients.

- Delayed injection site reactions included pain, erythema and swelling and are likely related to vaccination.

Federal COVID-19 Vaccination Program

- This vaccine is being made available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program);
- Vaccination providers may not charge vaccine recipients any fee for the vaccine and may not charge the vaccine recipient any charge for administration, although they may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees;
- How to report potential violations of the CDC COVID-19 Vaccination Program requirements.

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 updated to clarify that those that receive a COVID19 Vaccine cannot be charged, although vaccination providers may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees; how to report cases of suspected fraud; and other minor editorial changes.

We concur with the following changes to the label for the cartons of the vials containing a maximum of 11 doses:

- Contents: 10 multiple-dose vials (each multiple-dose vial contains a maximum of 11 doses 0.5mL each)
- Store Frozen between -50º to -15ºC (-58º to 5ºF)
- Discard after 12 hours
- Each multiple-dose vial contains a maximum of 11 doses (0.5mL each)

We concur with the following changes to the label for the vials containing a maximum of 11 doses:

- Multiple-dose vial (maximum 11 doses of 0.5mL)
- Store Frozen between -50º to -15ºC (-58º to 5ºF)
- Discard after 12 hours

We also concur with your carton and vial labels submitted for the ‘maximum of 15 doses’ presentation.

We also concur with the Chemistry Manufacturing and Controls (CMC) changes implemented to include an additional multidose vial presentation containing a maximum of 15 doses and related changes to the manufacturing process, drug product specifications and drug product storage conditions.

By submitting these amendments for review and concurrence by the Food and Drug Administration (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