



Our Reference: EUA 27073

Amended Emergency Use Authorization – Concurrence
NOVEMBER 19, 2022

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

Dear Dr. Olsen:

Please refer to your Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine, re-issued on October 12, 2022, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer you to your EUA amendments

- submitted and received on August 15, 2022 (EUA 27073/482)
- submitted and received on August 23, 2022 (EUA 27073/486)
- submitted and received on August 24, 2022 (EUA 27073/491)
- submitted and received on August 26, 2022 (EUA 27073/494)
- submitted and received on August 30, 2022 (EUA 27073/499)
- submitted and received on September 06, 2022 (EUA 27073/508)
- submitted and received on September 16, 2022 (EUA 27073/522)
- submitted and received on November 15, 2022 (EUA 27073/584)

Based on our review of the available data and information, we have determined that the following Moderna COVID-19 Vaccine, Bivalent batch manufactured at Catalent Indiana LLC (Catalent), Bloomington, IN, is suitable for use and meets the EUA standard, which is outlined in your Letter of Authorization. Thus, we concur with your request to add this batch to the EUA.

Manufacturer Batch #: 044H22-2A.

This concurrence does not add any other Moderna COVID-19 Vaccine, Bivalent batch manufactured at this facility to the EUA at this time and does not add the facility itself (for manufacture of Moderna COVID-19 Vaccine, Bivalent) to the EUA at this time.

We remind you that any changes that you plan to implement to the description of the product, manufacturing process, facilities, or equipment, will need to be submitted as an amendment to the EUA and not implemented without concurrence by the Agency.

If you have any questions, please contact the Regulatory Project Manager, Sudhakar Agnihothram, PhD at 202-870-6949.

Sincerely,

--/S/--

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research