U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27073

Amended Emergency Use Authorization – Concurrence
SEPTEMBER 20, 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 August 31, 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 27073/519 & 522)
- submitted and received on September 20, 2022 (EUA 27073/526)

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

Manufacturer's Batch #:
057F22A, 059F22A, 060F22A, 062F22A, 053D22A, 027E22A, 050D22A, 051D22A, 055F22B, and 030G22B.

This concurrence does not add any other Moderna COVID-19 Vaccine, Bilavent, batches manufactured at this facility to the EUA at this time. As noted in FDA's August 31, 2022, EUA decision memorandum for Moderna COVID-19 Vaccine, Bivalent, the Catalent manufacturing facility was not included as a facility authorized to manufacture Moderna COVID-19 Vaccine, Bivalent at that time because we were not able to assess

the facility's adequacy due to an ongoing FDA inspection. FDA intends to further consider the inclusion of the Catalent manufacturing facility following completion of its review of the inspectional information and any other pertinent information.

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
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research