Our Reference: EUA 27073

Amended Emergency Use Authorization – Concurrence
NOVEMBER 04, 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 October 31, 2022 (EUA 27073/573)
- submitted and received on November 4, 2022 (EUA 27073/577)

In summary, your amendments describe the following Chemistry, Manufacturing and Controls (CMC) changes to the manufacturing process of Moderna COVID-19 Vaccine:

i) Information and data to support the extension of the shelf-life of selected mRNA-1273 Drug Product lots from 9 months to 12 months when stored at recommended long-term storage conditions of -50 °C to -15 °C. This duration may include up to 30 days of storage at 2 °C – 8 °C and up to 24 hours of storage at room temperature (25 °C).

ii) Current shelf-life expiry dates and the extended shelf-life expiry dates for the Drug Product lots are provided below.

Lot Numbers	Current Shelf-Life Expiry Dating	Extended Shelf-Life Expiry Dating
054A22A	November 1, 2022	February 1, 2023
055A22A	November 2, 2022	February 2, 2023
057A22A	November 6, 2022	February 6, 2023
056A22A	November 7, 2022	February 7, 2023
059A22A	November 9, 2022	February 9, 2023
058A22-2A	November 10, 2022	February 10, 2023
060A22A	November 10, 2022	February 10, 2023

014B22A	November 11, 2022	February 11, 2023
015B22A	November 12, 2022	February 12, 2023
016B22A	November 13, 2022	February 13, 2023
017B22A	November 14, 2022	February 14, 2023
011B22A	November 18, 2022	February 18, 2023

We have completed our review and, based on the information submitted, we concur with these changes. 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,

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