

Our STN: BL 125752/0

## ACKNOWLEDGEMENT

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

June 9, 2021

Dear Ms. Olsen:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (PHS Act) for the following biological product:

**Our Submission Tracking Number (STN):** BL 125752

**Name of Biological Product:** COVID-19 mRNA Vaccine

**Indication:** Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

**Date of Application:** May 28, 2021

**Date of Receipt:** May 28, 2021

We have received your application submitted under provision (c) of Section 506 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 356) for review of an incomplete application for a Fast Track Product. We acknowledge your schedule for submission of the remaining portions of this application. In accordance with this section of the FDCA, our review clock will not start until the date on which you submit the final portion and inform us that your application is complete.

Please note that you are also responsible for complying with the applicable provisions of sections 402(i) and (j) of the PHS Act (42 U.S.C. §§ 282(i) and (j)), which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat.904).

All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to either the CBER Document Control Center at <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper> or the Electronic Submission Gateway at <https://www.fda.gov/electronic-submissions-gateway>.

Please note that the Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>.

The Center for Biologics Evaluation and Research (CBER) strongly encourages the use of secure email. Secure email makes use of encryption during transmission and the messages are decrypted upon receipt using the certificate. To establish secure email, please follow the instructions in SOPP 8119 *Use of Email for Regulatory Communications*, Appendix A available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm109645.htm>.

If you have any questions, please contact the Regulatory Project Manager, Sudhakar Agnihothram, Ph.D. at (301) 796-2640 or via email at [Sudhakar.Agnihothram@fda.hhs.gov](mailto:Sudhakar.Agnihothram@fda.hhs.gov).

Sincerely,

Rakesh Pandey, Ph.D.  
Chief  
Regulatory Review Branch 2  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research