CONCURRENCE PAGE

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Application #: STN: BL 125752/0

Communication Name: Filing Notification

Communication ID: LTR-BLAFILE-02

Instructions for entering communication into the appropriate regulatory system:
Letter Type: Filing Notification (FL)
No Deficiencies Identified (NDI)

Drafted by: Jo Resnick: 10/4/21

Review History:
Sudhakar Agnihothram: 10/6/21
Joe Kulinski: 10/05/21
Timothy Fritz: 10/07/21
Rakesh Pandey:10/12/2021
Kirk Prutzman: 10/06/21

Concurrence:
Chair: Sudhakar Agnihothram: 10/6/21
Branch Chief: Rakesh Pandey: 10/12/21
CSO: David Dickerson: 10/13/2021

cc: CBER Electronic Repository

END OF CONCURRENCE PAGE

The letter begins on the next page.

Our STN: BL 125752/0

FILING NOTIFICATION

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

October 14, 2021

Dear Dr. Olsen:

Please refer to your final portion of your rolling Biologics License Application (BLA) submitted and received August 24, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

We also refer to your initial portions of your rolling BLA submitted and received May 28, 2021 and August 16, 2021.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), we have filed your application today. The review classification for this application is **Priority**, the review goal date is April 24, 2022. This acknowledgment of filing does not mean that we have issued a license, nor does it represent any evaluation of the adequacy of the data submitted.

However, we plan to act early on this application under an expedited review, provided that no significant application deficiencies or unexpected shifts in work priorities or team staffing prevent an early action.

This application is also subject to the provisions of "the Program" under the Prescription Drug User Fee Act (PDUFA). Refer to https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserfee/ucm446608.htm.

We are reviewing your application according to the processes described in the guidance for industry and review staff *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). We plan to hold our internal mid-cycle review meeting on December 8, 2021. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of

any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by March 25, 2022.

This date conforms to the Managed Review Process timeline for your application. If our review continues an expedited timeline, we may communicate revised dates for labeling and postmarketing requirement/commitment requests.

At this time, we are still assessing if we will be discussing this application at an Advisory Committee meeting. We expect to notify you of a decision shortly.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge you have addressed PREA for this application.

If you have any questions, please contact the Regulatory Project Managers, Josephine Resnick, Ph.D., (Email: Josephine.Resnick@fda.hhs.gov) and Joseph Kulinski, Ph.D., (Email: Joseph.Kulinski@fda.hhs.gov) at (301) 796-2640.

Sincerely,

Loris D. McVittie, Ph.D.
Deputy Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research