



Our STN: BL 125869/0

REFUSAL TO FILE
February 3, 2026

ModernaTX, Inc.
Attention: (b) (6)
325 Binney Street
Cambridge, MA 02142

Dear (b) (6) :

Please refer to your Biologics License Application (BLA) received December 5, 2025, submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine, mRNA (b) (4) .

We have completed an initial review of your application to determine its acceptability for filing. We have determined that it is not sufficiently complete to enable a substantive review. Please note that this filing review represents a preliminary review of the application and is not indicative of deficiencies that would be identified later in a review cycle.

Under 21 CFR 601.2(a), “an application for a biologics license shall not be considered as filed until all pertinent information and data have been received by the Food and Drug Administration.” This section of the regulations lists all the information necessary to be submitted by the applicant. In addition, SOPP 8404 *Refusal to File Procedures* at <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/UCM600660.pdf> provides additional information on these submission requirements.

We are refusing to file this application under 21 CFR 601.2(a) for the following reasons:

1. CBER does not consider the application to contain a trial “adequate and well-controlled” and the application is therefore, on its’ face, inadequate for review. This is because your control arm does not reflect the best-available standard of care in the United States at the time of the study. I note that this determination is consistent with FDA’s advice given to you prior to your study.

Under section 736(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FDCA) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA), even you were required to pay the full fee required by subparagraph (A) upon submission of your application. Under section 736(a)(1)(D) of the FDCA, you will

receive a refund of 75 percent of the fee paid under subparagraph (B) because we refused to file your application.

If you disagree with our refusal to file decision, we strongly recommend, that within 30 days of the date of this letter, you request in writing a Type A meeting about our refusal to file the supplement. A meeting package should be submitted in accordance with SOPP 8101.1 *Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants* at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm>. To file this application over FDA's protest, you must avail yourself of this meeting. Please refer to SOPP 8404.1 *Procedures for Filing an Application When the Applicant Protests a Refusal to File Action (File Over Protest)* at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073478.htm>.

If, after the meeting, you still do not agree with our conclusions, you may request that the application be filed over protest. In that case, the suspended review clock will resume from the date which we received your request to file the application over protest. The application will be considered a new original application for user fee purposes, and you must remit the full fee or obtain a waiver. Please refer to guidance for industry *User Fee Waivers, Reductions and Refunds for Drugs and Biological Products* for additional information at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fee-waivers-reductions-and-refunds-drug-and-biological-products>.

If you have any questions, please contact the (b) (4)

by email.

Sincerely,

**VINAYAK K.
PRASAD -S**

Digitally signed by VINAYAK
K. PRASAD -S
Date: 2026.02.03 16:11:31
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Vinayak Prasad, MD, MPH
Director
Center for Biologics Evaluation and Research