

**Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)**

MEMORANDUM

Date: April 14, 2023

To: EUA 27073

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Applicant: Moderna TX, Inc.

Application Number: EUA 27073

Products: Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent

Subject: Change in Condition of Authorization to Require Reporting of Distribution Data

This review memorandum documents CBER's rationale for revising the Letter of Authorization (LOA) for Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent to require, under the conditions of authorization, reporting of vaccine distribution data.

Summary of Issue

Since initial EUA authorization, CBER has received vaccine administration data for Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent from the Centers for Disease Control and Prevention (CDC). This data was compiled by CDC based on information received from State public health agencies. Many States will no longer be providing this information to CDC beginning in May 2023. Thus, complete vaccine administration data will no longer be available to the agency after May 2023. The vaccine administration data was utilized by FDA as part of their safety surveillance efforts. In the absence of complete vaccine administration data, vaccine distribution data would similarly provide context for postmarketing adverse events, calculation of reporting rates for adverse events of special interest, and

observed-to-expected analyses. Accordingly, requiring the sponsor to submit vaccine distribution data is appropriate to protect the public health.

Therefore, Condition G in the LOA will be modified to require the inclusion of distribution data for Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent in the monthly periodic safety reports. The sponsor has already submitted its periodic safety report due in April 2023, so this information would be included in periodic safety reports due in May 2023 or subsequent months. Of note, the sponsor is already required, under a condition of authorization (Condition L), to “maintain records regarding release of Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent for distribution (i.e., lot numbers, quantity, release date).”

Summary of changes to LOA Condition of Authorization

The Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent LOA, Conditions of Authorization, describe the requirement for sponsor submission of periodic safety reports at monthly intervals (Condition G). For the reasons described in this memorandum, Condition G will be revised to require reporting of vaccine distribution data.

The revised Condition G will be as follows (the new reporting requirement is in bold font):

ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports monthly, in accordance with a due date agreed upon with the Office of Biostatistics and Pharmacovigilance (OBPV)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:

- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval;
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated); and
- **Cumulative doses distributed, and doses distributed during the monthly reporting interval, for Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent.**

Conclusions

- CBER determined that in the absence of vaccine administration data, it will be important to have vaccine distribution data submitted by the sponsor, to aid analyses of postmarketing safety data.
- Condition G of the LOA will be revised to require submission of distribution data in monthly periodic safety reports.