Food and Drug Administration
Center for Biologics Evaluation and Research
Division of Manufacturing and Product Quality

From: Obinna Echeozo, CMC/Facility Reviewer, OCBQ/DMPQ/MRB2

To: Administrative File STN: 125752/0

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Applicant: ModernaTx, Inc.

Product: COVID-19 Vaccine, SPIKEVAX (administered intramuscularly)

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

Subject: Recommendation to waive pre-license inspections (PLIs)

Due Date: 23 February 2022

The following information provides justification to support the waiver recommendations:

Inspection history:

Location	Activity	Most Recent Inspection
Catalent Biologics, LLC, 1300 S. Patterson Drive, Bloomington, IN 47403 (FEI#: 3005949964)	Manufacturing of drug product (DP), in-process testing, release testing (sterility), storage.	PLI CDER September 2020 VAI
Baxter Pharmaceutical Solutions, LLC., 927 S Curry Pike Bloomington IN 47403 (FEI#: 1000115571)	Manufacturing of DP, in-process testing, release testing (sterility), storage.	Surveillance ORA/OBPO November 2021 VAI
Associates of Cape Cod 124 Bernard E. Saint Jean Drive East Falmouth, MA 02536 (FEI#: 1219145)	DP release testing (bacterial endotoxin)	Surveillance ORA November 2019 VAI

VAI = Voluntary Action Indicated
CDER = Center for Drug Evaluation and Research
ORA = Office of Regulatory Affairs
OBPO = Office of Biological Products Operations

For the subject BLA, the following manufacturing facilities are proposed for an inspection waiver.

Catalent Biologics, LLC (Catalent), Bloomington:

Catalent is a contract manufacturing organization (CMO) located in Bloomington, Indiana. The Catalent Bloomington manufacturing facility is an existing facility used for the aseptic fill/finish, in-process testing, release testing (sterility) and storage of Moderna's mRNA-1273 DP. The facility is a multi-product facility currently approved for the manufacture of sterile-filled small volume parenteral drugs, mammalian cell line and various chemical/biological DP formulations. Catalent Bloomington is approved for the manufacture of aseptically filled biologic product.

The Catalent Bloomington facility has a known FDA compliance history. The last ten inspections of this facility were designated either VAI or no action indicated (NAI). The most recent FDA inspection of the site was conducted by CDER from August 27 – September 2, 2020 which covered manufacturing areas, equipment, and processes that are relevant to the subject BLA submission and was classified as VAI. No modifications to the facility and equipment were made since the most recent FDA inspection under this BLA.

Baxter Pharmaceutical Solutions, LLC, (Baxter) Bloomington:

The Baxter Bloomington facility is an existing multi-product facility for the aseptic fill/finish, in-process testing, release testing (sterility) and storage of Moderna's mRNA-1273 DP. Baxter Bloomington is a CMO currently approved to manufacture small volume parenteral, aseptically filled, freeze-dried, and terminally sterilized biologic/chemical products.

Baxter Bloomington was recently inspected by ORA/OBPO from November 02 – 10, 2021. The inspection covered manufacturing areas, equipment, and processes relevant to the subject BLA, and was classified as VAI. Baxter Bloomington has a known FDA compliance history. The last ten inspections were designated either VAI or NAI.

Associates of Cape Cod (ACC), East Falmouth

ACC East Falmouth is an existing contract testing facility responsible for bacterial endotoxin final release testing of Moderna's mRNA-1273 DP. ACC has a known FDA compliance history. The most recent FDA inspection covering endotoxin testing processes at ACC was conducted on November 19 – 26, 2019 and was classified VAI. Also, the last ten inspections were designated either VAI or NAI.

Recommendation: Waive PLIs of the aforementioned facilities.

Concurrence signatures:

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