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BLA Number 125752
Sequence No. 0001

May 28, 2021

Marion Gruber, PhD
Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Submission Type: First Rolling Review Submission for Biologics License Application (BLA) - mRNA-1273

Dear Dr. Gruber:

Reference is made to pre-assigned submission tracking number (STN) BLA 125752 for the initial Biologics License Application (BLA) for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2).

Further reference is made to IND 019745, submitted to FDA on 27Apr 2021, and EUA 27073 authorized on 18Dec2020 for Emergency Use for mRNA-1273 (Moderna COVID-19 Vaccine) under Sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013.

Final reference is made to discussions with CBER, in which Moderna received verbal agreement by FDA to initiate the BLA submission in a rolling fashion with Module 4 under Section 351 of the Public Health Service Act.

The purpose of this submission is to submit the Biologics License Application (BLA) for mRNA-1273 for the proposed indication of active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in persons 18 years of age and older. The contents of this submission are included in the table below.

Section	Study report #
1.1.2	Application form: FDA form 356h
1.1.3	User fee cover sheet: FDA form 3397
1.2	Cover Letter
4.2.1	MOD-4112
	VRC-01
	MOD-3937

	MOD-3938/MOD-3940
	VRC-05
	VRC-02
	UTMB01
	VRC-04
	VRC-07
4.2.2.3	5002121
4.2.3.2	5002045
	5002231
	5002033
	5002400
	5002034
	5002158
4.2.3.3.1	9601567
	9601568
	9601035
	9601036
4.2.3.3.2	9800399
	AF87FU.125012NGLPICH.BTL
4.2.3.5.2/3	20248897
4.2.3.7.2	2308123
4.3	Literature References

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 or at michelle.olsen@modernatx.com.

This eCTD submission has been prepared by PPD Development, Inc. in full compliance with ICH and FDA guidance. The eCTD has been verified and confirmed to be virus and spyware free. PPD utilizes Palo Alto Traps v4.2.2. All technical questions should be directed to (b) (6) at PPD (b) (6) or email at (b) (6).

Yours Sincerely,

Michelle Olsen Digitally signed by Michelle Olsen
Date: 2021.05.28 11:43:13 -04'00'

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