

IND Number 27073
Sequence No. 0001

November 30, 2020

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: Emergency Use Authorization Request – Moderna COVID-19 VACCINE

Dear Dr. Gruber:

Reference is made to pre-assigned submission tracking number (STN) EUA 27073 for Emergency Use Authorization of the new drug mRNA-1273.

The purpose of this submission is to submit the Emergency Use Authorization Request for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2).

This submission includes:

- 1.2 – Cover Letter
- 1.4.4 – Letter of Authorization for mRNA-1273
- 1.14.1.3 – Draft Fact Sheet for Health Care Providers combined with the Package Insert – Clean version
- 1.14.1.3 – Draft Fact Sheet for Health Care Providers combined with the Package Insert – Annotated version
- 1.14.1.3 – Draft Fact Sheet for Health Care Providers combined with the Package Insert – redline version
- 1.14.1.3 – Draft Fact Sheet for Patients – Clean version
- 1.14.1.3 – Draft Fact Sheet for Patients – redline version
- 1.19 - Emergency Use Authorization (EUA) Request for Moderna COVID-19 Vaccine
- 2.5 – Clinical Overview
- 5.3.5.1 – mRNA-1273-P301 – Narratives
- 5.3.5.1 – Medwatch Forms
- 5.4 – Literature References

If FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at (b) (6)@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,

**Carlota
Vinals**

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