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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
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Submission Type: Response to multiple comments: Clinical, Prescribing Information

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.

This submission includes:

1.2 Cover Letter

1.11.3 Response to Comments Regarding Clinical Topics – EUA IR #8 Q's 3 to 5

1.11.3 Response to Comments Regarding Clinical Topics – EUA IR #9 Q's 1 to 3

1.14.1.3 Draft EUA Prescribing Information (PI) (AR Tables Sections 11-21) – Clean and Redline

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,

Carla Vinals
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by Carla Vinals
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