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Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC
Pfizer Global Supply (PGS)
Specialty/ Biotechnology Operating Unit
Manufacturing Site
One Burtt Road
Andover, MA 01810 USA

(FEI Number: 1222181)

CONFIDENTIAL

August 01, 2021 QAC 21-01

Mr. John Eltermann
Director, Division of Manufacturing and Product Quality
U.S. Food and Drug Administration
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: **Response to U.S. Food and Drug Administration (FDA) FORM FDA 483, issued on July 23, 2021**

Dear Mr. Eltermann,

The U.S. FDA conducted the pre-license inspection for BLA 125742 (COVID-19 mRNA Vaccine) at the Pfizer Andover facility located in Andover, Massachusetts from July 19-23, 2021. Attached please find Pfizer's response to the FORM FDA 483 issued at the close of the inspection. This response includes the Agency's observations restated in bold font in the order presented in the FORM FDA 483, followed by Pfizer's response to each observation. We appreciate the feedback provided by the inspectors during the inspection.

Pfizer is committed to the delivery of safe and effective products to patients. The Pfizer Andover facility has a long history of the development and manufacture of products and meets the needs of patients around the world through scientific excellence and a commitment to quality. The site maintains a strong quality culture and oversight with appropriate systems and processes in place to drive quality-focused behaviors and ensure decision making based on what is best for product quality, patient safety, and compliance with current Good Manufacturing Practices. We are confident in our batch release process and that our on-going compliance with that process assures the product released to the market is of the highest quality. Programs are in place to ensure rigorous environmental monitoring, cleaning, and maintenance of the facility, and we remain committed to continuous improvement initiatives and enhancements to the facility to ensure continuing compliance.

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At the request of the Agency, Pfizer is expediting this comprehensive response to the FORM FDA 483 observations. We are confident these responses demonstrate Pfizer's understanding of and commitment to quality and continuous improvement and adequately address the observations raised by the Agency. We are available to meet with the Agency to address any questions or provide supplemental information as needed.

Please note that effective July 26, 2021, Amy Lovasco replaced Jon Tucker as the Andover Site Leader, in interim capacity. If you require additional information, please do not hesitate to contact Amy Lovasco at (b) (6) or (b) (6)

Sincerely,

DocuSigned by:
Amy Lovasco
Signer Name: Amy Lovasco
Signing Reason: I approve this document
Signing Time: 01-Aug-2021 | 1:04:39 PM E(b) (6)
BC18EC9CF2CA4E3995C02D42CDBD7[redacted]

Amy Lovasco
Interim Site Leader

DocuSigned by:
(b) (6)
Signer Name: (b) (6)
Signing Reason: I approve this document
Signing Time: 01-Aug-2021 | 1:00:08 PM EDT
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cc: Kathleen Jones, Biologist, CBER/OCBQ/DMPQ/B1

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