Stevanato Group

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To: **Food and Drug Administration**
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
Building 71, Room G112
Silver Spring, MD 20993-0002

Copy to **Pfizer Inc. as US Agent for BioNTech RNA**
Pharmaceuticals GmbH
500 Arcola Road
Collegeville, PA 19436
USA

Piombino Dese (Italy), August 25, 2020

DMF Type III no. #011321
Submission date: Submitted on January 15, 1995 – revised on May 22, 2015
DMF Holder: Stevanato Group S.p.A.
Letter of authorization for: 0612090.5636 – VIAL VB 2mL 16.25x0.85x31

Dear DMF Staff,

Stevanato Group S.p.A. hereby authorizes **Pfizer Inc.** to incorporate by reference information **0612090.5636 – VIAL VB 2mL 16.25x0.85x31**in DMF Type III #011321 into **any application** filed by **Pfizer Inc.** We also authorize the FDA to review the aforementioned specific information in DMF Type III #011321 when considering **any application** filed by **Pfizer Inc.**

Item: 0612090.5636 – VIAL VB 2mL
Drug product: SARS-COV-2-mRNA Vaccine
Drawing: 5636/05-02
Referenced Section: Module 3, Section 3.2.P.1 List of products ANNEX A Attachment 530

Stevanato Group S.p.A states that DMF Type III #011321 is current and Stevanato Group S.p.A will comply with the statements made within it. Stevanato Group S.p.A will notify FDA through an amendment to DMF#011321 of any addition, change, or deletion of information in the DMF. Stevanato Group S.p.A will also notify in writing **Pfizer Inc.** that an addition, change, or deletion of information has been made to the DMF.

Sincerely,

Andrea Salmaso
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