



Our STN: BL 125742/44

SUPPLEMENT APPROVAL

January 14 , 2022

BioNTech Manufacturing GmbH
Attention: Adrienne Stafford
Pfizer Global CMC – Vaccines
4300 Oak Park Road
Sanford, NC 27330

Dear Ms. Stafford:

We have approved your request submitted and received December 17, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA to add 30 µg Tris/Sucrose formulated drug product manufacturing in Building ^{(b) (4)}, with fill and finish operations on Line ^{(b) (4)} at the Pharmacia and Upjohn Company LLC facility in Kalamazoo, MI.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

(b) (6)

Center for Biologics Evaluation and Research