



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,

**Carolyn A.  
Renshaw -S**

Digitally signed by Carolyn A. Renshaw -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People,  
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cn=Carolyn A. Renshaw -S  
Date: 2022.01.14 12:39:41 -05'00'

Carolyn Renshaw  
Acting Director  
Division of Manufacturing and Product Quality  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research