



Our STN: BL 125742/67

SUPPLEMENT APPROVAL

BioNTech Manufacturing GmbH
Attention: Adrienne Stafford
Pfizer Inc.
4300 Oak Park Road
Sanford, NC 27330

April 14, 2022

Dear Ms. Stafford:

We have approved your request received on March 14, 2022, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs), Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan (Pfizer, Kalamazoo) and Hospira, Inc., McPherson, Kansas (Pfizer, McPherson) facilities, to extend the expiry dating period for the 30 µg dose of Tris/Sucrose formulation (filled at Pfizer, Puurs and Pfizer, Kalamazoo facilities) from 9 months to 12 months when stored between -90 °C to -60 °C.

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

Sincerely,

/s/

Digitally signed
by Jerry P. Weir -S
Date: 2022.04.14
13:18:21 -04'00'

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
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