IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

BENJAMIN COKER, *et al.*, Plaintiffs, v. **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,** Defendants.	Case No. 3:21-cv-01211-AW-HTC

DECLARATION OF SUZANN BURK

I, Suzann Burk, declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of documents officially maintained by CBER, the center in FDA that regulates biologic products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine and one-half years. Prior to that, I was a member of the Congressional and Oversight Branch in DDOM for two years and a member of the Access Litigation and Freedom of Information Branch in

DDOM for four years.

3. In my capacity as Director of DDOM I have access to official CBER documents. I am responsible for disclosing documents in litigation on behalf of CBER.

4. I submit this declaration in support of Defendants' Motion to Dismiss and I understand this declaration may be used in other cases as well. The statements made in this declaration are based on my personal knowledge and official records available to me in my official capacity.

5. Attached hereto as Exhibit 1 is a copy of redacted pages from the lot release protocol for Lot FW1331 of Comirnaty. I certify that Exhibit 1 consists of copies of pages from an official FDA record.

6. I declare under penalty of perjury that the foregoing Exhibit 1 and the facts contained in this declaration are true and correct pursuant to 28 U.S.C. § 1746.

Suzann H. Burk -S Digitally signed by Suzann H. Burk -S
Date: 2022.08.24 11:21:13 -04'00'

SUZANN BURK
Division Director
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

Executed on August 24, 2022

Reason for Submission
For Release

cc: STN 125742-36/2229/FC

Lot Number: FW1331
License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Formulation: Tris/Sucrose

Manufacturer Name: Pharmacia & Upjohn Company LLC for BioNTech Manufacturing GmbH

Manufacturer Address: 7000 Portage Rd., Kalamazoo, MI 49001 USA

Trade name: COMIRNATY

Date of Manufacturing: 28-Jan-2022 **Expiration Date:** 30-Sep-2022

Fill Information

Container Type:	Vial	**Volume per container:**	2.25 mL
Approved Storage Period:	9 months	**Storage Temperature:**	-90°C to -60°C
Number of containers manufactured:	(b) (4)	**Number of Doses per container:**	10
Number of containers for release:	(b) (4)		
Volume of single human dose:	30 µg/Dose	**Start Date of period of Validity:**	Date of Manufacture

All tests conducted on this lot are reported and pass specifications as required.

Signature: DocuSigned by: R Marty Kenny
Signer Name: R Marty Kenny
Signing Reason: I approve this document
Signing Time: 07-Apr-2022 | 9:53:09 PM EDT
C22F83DD74364E6B9223F89FEC207203

Date: 07-Apr-2022

Title: Manager, Quality Operations
Electronic Protocol # - 20229002.P0

cc: STN 125742-36/2229/FC

Lot Number: FW1331

License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Formulation: Tris/Sucrose

Manufacturing Site: Pharmacia & Upjohn Company LLC, 7000 Portage Rd., Kalamazoo, MI 49001 USA

Date of Manufacture: 28-Jan-2022 **Date of Expiry:** 30-Sep-2022

Date of Fill: 31-Jan-2022

Product Information:

Drug Substance Target Concentration: (b) (4) mg/mL

COMPONENTS

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity
BNT162b2 Drug Substance	(b) (4)	17-Nov-2021	Pfizer ACMF	(b) (4)
LNP Fabrication and Bulk Drug Product Formulation	(b) (4)	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Filling/Inspection	(b) (4)	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Packaging	FW1331	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)