

## CONCURRENCE PAGE

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**Application #:** STN: BL 125742/0

**Communication Name:** Unique Ingredient Identifier (UNII) Code Assignment

**Communication ID:** LTR-BLAUNI-01

**Instructions for entering communication into the appropriate regulatory system:**

Letter Type: UNII Code Notification (UNI)

Summary Text: Unique Ingredient Identifier (UNII) Code Assignment

**Drafted by:** Mike Smith 8/5/2021

**Review History/Concurrence:**

M, Smith:

R. Naik: 8/5/2021

L. Gottschalk: 8/5/2021

E. Sutkowski: 8/5/2021

**cc:** CBER Electronic Repository

**END OF CONCURRENCE PAGE**

**The letter begins on the next page.**



Our STN: BL 125742/0

**UNIQUE INGREDIENT IDENTIFIER  
(UNII) CODE ASSIGNMENT**  
August 6, 2021

BioNTech Manufacturing GmbH  
Attention: Elisa Harkins  
Pfizer Inc.  
500 Arcola Road  
Collegetown, PA 19426

Dear Ms. Harkins:

The Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) (FDAAA) requires that establishment registration and drug listing be accomplished electronically. To facilitate your electronic establishment registration and drug listing process, we have assigned Unique Ingredient Identifier (UNII) codes for your product, COVID-19 Vaccine, mRNA.

**Active Ingredient/Active Moiety/  
Basis of Strength:**

BNT162b2 drug substance

**UNII:**  
5085ZFP6SJ

**Excipients:**

ALC-0159  
ALC-0315  
POTASSIUM CHLORIDE  
MONOBASIC POTASSIUM PHOSPHATE  
SODIUM CHLORIDE  
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM  
SUCROSE  
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE  
CHOLESTEROL  
WATER

**UNII:**  
PJH39UMU6H  
AVX8DX713V  
660YQ98I10  
4J9FJ0HL51  
451W47IQ8X  
GR686LBA74  
C151H8M554  
043IPI2M0K  
97C5T2UQ7J  
059QF0KO0R

Please be aware that your UNII codes and substance name have been published on our Structured Product Labeling Resources website at <https://www.fda.gov/industry/fda-resources-data-standards/structured-product-labeling-resources>. If you need to contact us, please refer to BL 125742/0.

UNII codes are a part of the joint United States Pharmacopeia (USP)/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information.

These names and identifiers are accessible through the USP website at <http://www.usp.org> and USP publications, the Data Standards Council website at <https://www.fda.gov/industry/fda-resources-data-standards/fda-data-standards-council> and the NCI Thesaurus website at <http://evs.nci.nih.gov>.

If you have any questions, please contact me at 301-796-2640 or [Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov).

Sincerely,

CAPT Mike Smith, Ph.D.  
Regulatory Project Manager  
Division of Vaccines and  
Related Product Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research