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.
BioNTech Manufacturing GmbH  
Attention: Elisa Harkins  
Pfizer Inc.  
500 Arcola Road  
Collegeville, 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:**  

<table>
<thead>
<tr>
<th>Substance</th>
<th>UNII</th>
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<tbody>
<tr>
<td>ALC-0159</td>
<td>PJH39UMU6H</td>
</tr>
<tr>
<td>ALC-0315</td>
<td>AVX8DX713V</td>
</tr>
<tr>
<td>POTASSIUM CHLORIDE</td>
<td>660YQ98I10</td>
</tr>
<tr>
<td>MONOBASIC POTASSIUM PHOSPHATE</td>
<td>4J9FJ0HL51</td>
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<tr>
<td>SODIUM CHLORIDE</td>
<td>451W47IQ8X</td>
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<tr>
<td>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</td>
<td>GR686LBA74</td>
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<tr>
<td>SUCROSE</td>
<td>C151H8M554</td>
</tr>
<tr>
<td>1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE</td>
<td>043IPI2M0K</td>
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<td>CHOLESTEROL</td>
<td>97C5T2UQ7J</td>
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<tr>
<td>WATER</td>
<td>059QF0KO0R</td>
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</tbody>
</table>

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](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.

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