REQUEST FOR PROPRIETARY &
NON-PROPRIETARY NAME REVIEW
TABLE OF CONTENTS

1. APPLICANT CONTACT INFORMATION ......................................................... 3
2. PROPOSED PRIMARY AND ALTERNATE PROPRIETARY NAMES .......... 3
3. INTENDED PRONUNCIATION .................................................................... 3
4. DERIVATION OF PROPRIETARY NAME .................................................. 3
5. INTENDED MEANING OF PROPRIETARY NAME MODIFIERS ............... 3
6. PROPOSED ESTABLISHED NAME .............................................................. 3
7. PHARMACOLOGIC/ THERAPEUTIC CATEGORY ........................................ 3
8. PROPOSED INDICATION FOR USE ........................................................... 3
9. PRESCRIPTION STATUS ............................................................................ 4
10. DOSAGE FORM, PRODUCT STRENGTH(S) ............................................... 4
11. ROUTE OF ADMINISTRATION ................................................................. 4
12. USUAL DOSAGE, FREQUENCY OF ADMINISTRATION, MAXIMUM DAILY DOSE .......................................................... 4
13. DOSING IN SPECIFIC POPULATIONS ....................................................... 4
14. INSTRUCTIONS FOR USE ..................................................................... 4
15. STORAGE REQUIREMENT ...................................................................... 4
16. HOW SUPPLIED AND PACKAGING CONFIGURATION ............................. 4
17. LIKELY CARE ENVIRONMENT(S) FOR DISPENSING AND USE .............. 5
18. DELIVERY SYSTEM, MEASURING DEVICE ............................................. 5
19. ASSESSMENTS OF PROPRIETARY NAME, PACKAGING, AND/OR LABELING .................................................. 5
1. APPLICANT CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Name and title of contact</th>
<th>Elisa Harkins, Senior Director, Global Regulatory Affairs, Pfizer, Inc. – Authorized US Agent for: BioNTech Manufacturing GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name</td>
<td>Pfizer Inc.</td>
</tr>
<tr>
<td>Address</td>
<td>500 Arcola Road, Collegeville, PA 19426</td>
</tr>
<tr>
<td>Phone number</td>
<td>215-280-5503</td>
</tr>
<tr>
<td>Fax number</td>
<td>845-474-3500</td>
</tr>
<tr>
<td>Email address</td>
<td><a href="mailto:Elisa.HarkinsTull@pfizer.com">Elisa.HarkinsTull@pfizer.com</a></td>
</tr>
</tbody>
</table>

2. PROPOSED PRIMARY AND ALTERNATE PROPRIETARY NAMES

The primary proposed proprietary name for Agency consideration is COMIRNATY.

The trademark application serial number is 88942267 (filed by BioNTech SE) for COMIRNATY. The application was filed at the United States Patent and Trademark Office on June 1, 2020 by BioNTech SE. The Notice of Allowance has not yet issued.

Should this name not be found acceptable, an alternate name will be provided at that time.

3. INTENDED PRONUNCIATION

koh-MER’ nah-tee

4. DERIVATION OF PROPRIETARY NAME

The proposed proprietary name COMIRNATY is an invented word with no inherent meaning.

5. INTENDED MEANING OF PROPRIETARY NAME MODIFIERS

Not applicable.

6. PROPOSED ESTABLISHED NAME

COVID-19 mRNA Vaccine (nucleoside modified)

7. PHARMACOLOGIC/ THERAPEUTIC CATEGORY

Prophylactic vaccine.

8. PROPOSED INDICATION FOR USE

Active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus, in individuals 16 years of age and older.
9. PRESCRIPTION STATUS
To be administered by a qualified healthcare professional.

10. DOSAGE FORM, PRODUCT STRENGTH(S)
Concentrate for solution for injection.

5-Dose Vial is supplied as a white to off-white sterile frozen liquid, packaged in a clear glass
2 mL vial with a rubber stopper, aluminum overseal and flip off cap.

A single vial will be used to prepare a diluted dosing solution that is used to prepare doses for
multiple individuals. The concentrated solution in the vial requires dilution with sterile 0.9%
Sodium Chloride Injection, USP. After dilution, the vials contain a sufficient volume to
supply 5 doses, where each 0.3 mL dose contains 30 µg vaccine for intramuscular injection.

11. ROUTE OF ADMINISTRATION
For intramuscular injection only.

12. USUAL DOSAGE, FREQUENCY OF ADMINISTRATION, MAXIMUM DAILY
DOSE
Administered intramuscularly as a series of two 30 µg doses of the diluted vaccine solution
(0.3 mL each) according to the following schedule: A single 0.3 mL dose followed by a
second 0.3 mL dose 21 days later.

13. DOSING IN SPECIFIC POPULATIONS
No specific information will be provided for modifications that are dependent on renal and/or
hepatic function. There will be no gender-based modifications.

14. INSTRUCTIONS FOR USE
After thawing, each vial of vaccine must be diluted with 1.8 mL sterile 0.9% Sodium
Chloride Injection, USP. After dilution, the vial contains five 30 µg doses of 0.3 mL per
dose. Individual 0.3 mL doses should be withdrawn from the vial and administered
intramuscularly in the deltoid muscle of the non-dominant arm.

15. STORAGE REQUIREMENT
Vaccine vials must be immediately stored between -80 °C and -60 °C (-112 °F to -76 °F),
protected from light and kept in the original packaging until ready for use.

16. HOW SUPPLIED AND PACKAGING CONFIGURATION
The vaccine will be supplied frozen in -80 °C thermal containers with dry ice, in cartons each
containing 195 vials.
17. LIKELY CARE ENVIRONMENT(S) FOR DISPENSING AND USE
This vaccine will be administered by a qualified healthcare professional.

18. DELIVERY SYSTEM, MEASURING DEVICE
After dilution, each 0.3 mL dose of vaccine should be withdrawn from the vial with a commercially available disposable sterile syringe with appropriate graduations and delivered with a needle appropriate for intramuscular injection.

19. ASSESSMENTS OF PROPRIETARY NAME, PACKAGING, AND/OR LABELING
The Sponsor has evaluated the proposed primary proprietary name of COMIRNATY for this vaccine and considers the name safe, not misleading, or over-promising. However, no information of this nature is included in the current application.