

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, Parts 314 & 601)</i>	Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2020 See PRA Statement on page 3. 1. Date of Submission (mm/dd/yyyy) 07/23/2021
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APPLICANT INFORMATION	2. Name of Applicant BioNTech Manufacturing GmbH
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3. Telephone Number (Include country code if applicable and area code) +49 (0) 6131 9084-7593	4. Facsimile (FAX) Number (Include country code if applicable and area code) +49 (0) 6131 9084-390
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5. Applicant Address			
Address 1 (Street address, P.O. box, company name c/o) An der Goldgrube 12		Email Address Ruben.Rizzi@biontech.de	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Applicant DUNS 117645848	
City Mainz	State/Province/Region N/A	U.S. License Number if previously issued 2229	
Country Germany	ZIP or Postal Code 55131		

6. Authorized U.S. Agent (Required for non-U.S. applicants)			
Authorized U.S. Agent Name Elisa Harkins, Global Regulatory Lead, Pfizer Global Regulatory Affairs - Vaccines		Telephone Number (Include area code) 215-280-5503	
Address 1 (Street address, P.O. box, company name c/o) 500 Arcola Road		FAX Number (Include area code) 845-474-3500	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Email Address Elisa.HarkinsTull@pfizer.com	
City Collegeville	State PA	U.S. Agent DUNS	
ZIP Code 19426			

PRODUCT DESCRIPTION	7. NDA, ANDA, or BLA Application Number 125742	8. Supplement Number (If applicable)
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9. Established Name (e.g., proper name, USP/USAN name) [COVID-19 mRNA Vaccine (nucleoside modified)]

10. Proprietary Name (Trade Name) (If any) COMIRNATY

11. Chemical/Biochemical/Blood Product Name (If any) COVID-19 Vaccine (BNT162, PF-07302048)
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12. Dosage Form Liquid	13. Strengths 30 mcg	14. Route of Administration Intramuscular
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15A. Proposed Indication for Use Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>	Continuation Page for #15

15B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term) COVID-19; SARS-CoV-2; Disease caused by severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 vaccination; COVID-19 vaccination
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APPLICATION INFORMATION	16. Application Type (Select one) <input type="checkbox"/> New Drug Application (NDA) <input checked="" type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Abbreviated New Drug Application (ANDA)
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17. If an NDA, identify the type <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)	18. If a BLA, identify the type <input checked="" type="checkbox"/> 351(a) <input type="checkbox"/> 351(k)
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19. If a 351(k), identify the biological reference product that is the basis for the submission. Name of Biologic: _____ Holder of Licensed Application: _____

20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission. Name of Drug: _____ Application Number of Relied Upon Product: _____
Indicate Patent Certification: <input type="checkbox"/> P1 <input type="checkbox"/> P2 <input type="checkbox"/> P3 <input type="checkbox"/> P4 <input type="checkbox"/> Section viii - MOU <input type="checkbox"/> Statement of no relevant patents

21. Submission (See instructions) <input checked="" type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report <input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report <input type="checkbox"/> Request for Proprietary Name Review <input type="checkbox"/> Other (Specify): _____			
22. Submission Sub-Type <input type="checkbox"/> Presubmission <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Initial Submission <input type="checkbox"/> Resubmission		23. If a supplement, identify the appropriate category. <input type="checkbox"/> CBE <input type="checkbox"/> Prior Approval (PA) <input type="checkbox"/> CBE-30	
24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No		Combination Product Type (See instructions)	Request for Designation (RFD) Number
25. Does the submission contain: Only Pediatric data? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Human factors information? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	26. Proposed Marketing Status (Select one) <input checked="" type="checkbox"/> Prescription Product (Rx) <input type="checkbox"/> Over-The-Counter Product (OTC)
27. Reasons for Submission Response to 15 July 2021 Information Request regarding PREA post-marketing commitment goal dates			
28. Establishment Information (Full establishment information should be provided in the body of the application.)			
Establishment Name Pharmacia and Upjohn Company LLC (Pfizer)			
Address 1 (Street address, P.O. box, company name c/o) 7000 Portage Road		Registration (FEI) Number 1810189	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Kalamazoo	State/Province/Region MI		Establishment DUNS Number 618054084
Country USA	ZIP or Postal Code 49001		
Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	
Establishment Contact Information at the site/facility			
Name of Contact for the Establishment (b) (6)		Telephone Number (Include area code) (b) (6)	
(b) (6)		FAX Number (Include area code) (b) (6)	
		Email Address (b) (6)	
		(b) (6)	
Manufacturing Steps and/or Type of Testing LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing		Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____	
		Continuation Page for #28	
29. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.) IND 19736, DMF 012683, DMF 9543, DMF 15209, DMF 011793, DMF 011820, DMF 011321, DMF 10953,			
Contin. Page for #29			
30. This application contains the following items (Select all that apply)			
<input checked="" type="checkbox"/> 1. Index <input type="checkbox"/> 2. Labeling (Select one): <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling <input type="checkbox"/> 3. Summary (21 CFR 314.50 (c))			
<input type="checkbox"/> 4. Chemistry Section <input type="checkbox"/> A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2) <input type="checkbox"/> B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) <input type="checkbox"/> C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)			
<input type="checkbox"/> 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)		<input type="checkbox"/> 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
<input type="checkbox"/> 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))		<input type="checkbox"/> 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
Item 30 continued on page 3			

30. This application contains the following items (Continued; select all that apply)

<input type="checkbox"/> 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	<input type="checkbox"/> 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
<input type="checkbox"/> 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	<input type="checkbox"/> 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input type="checkbox"/> 13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c))	<input type="checkbox"/> 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input type="checkbox"/> 15. Establishment description (21 CFR Part 600, if applicable)	<input type="checkbox"/> 16. Debarment certification (FD&C Act 306 (k)(1))
<input type="checkbox"/> 17. Field copy certification (21 CFR 314.50 (l)(3))	<input type="checkbox"/> 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)
<input type="checkbox"/> 19. Financial Disclosure Information (21 CFR Part 54)	
<input checked="" type="checkbox"/> 20. Other (Specify): <u>Response to 15 July 2021 Information Request regarding PREA post-marketing commitment goal dates</u>	

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

31. Typed Name and Title of Applicant's Responsible Official Elisa Harkins, Global Regulatory Lead, Global Regulatory Affairs - Vaccines, Pfizer Inc.	32. Date (mm/dd/yyyy) 07/22/2021
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33. Telephone Number (Include country code if applicable and area code) 215-280-5503	34. FAX Number (Include country code if applicable and area code) 845-474-3500	35. Email Address Elisa.HarkinsTull@pfizer.com
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36. Address of Applicant's Responsible Official			
Address 1 (Street address, P.O. box, company name c/o) 500 Arcola Road			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City Collegeville		State/Province/Region PA	
Country United States of America		ZIP or Postal Code 19426	

37. Signature of Applicant's Responsible Official or Other Authorized Official Elisa Harkins Tull <small>Digitally signed by Elisa Harkins Tull DN: o=Pfizer Inc, cn=Elisa Harkins Tull Reason: I attest to the accuracy and integrity of this document Date: 2021 07 22 17:03:38 -04'00'</small>	Sign	38. Countersignature of Authorized U.S. Agent	Sign
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Food and Drug Administration
Office of Operations
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PRAStaff@fda.hhs.gov

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FIRST CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name
Pfizer Manufacturing Belgium NV

Address 1 (Street address, P.O. box, company name c/o)
Rijksweg 12

Address 2 (Apartment, suite, unit, building, floor, etc.)

City
Puurs

State/Province/Region
N/A

Country
Belgium

ZIP or Postal Code
2870

Registration (FEI) Number
1000654629

MF Number

Establishment DUNS Number
370156507

Is the establishment new to the application? Yes No

What is the status of the establishment? Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment
(b) (6)

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

(b) (6)

Manufacturing Steps and/or Type of Testing
LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing

Is the site ready for inspection? Yes No N/A
If No, when will site be ready? (mm/dd/yyyy) _____

Establishment Name
Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC

Address 1 (Street address, P.O. box, company name c/o)
1 Burt Road

Address 2 (Apartment, suite, unit, building, floor, etc.)

City
Andover

State/Province/Region
MA

Country
United States

ZIP or Postal Code
01810

Registration (FEI) Number
1222181

MF Number

Establishment DUNS Number
174350868

Is the establishment new to the application? Yes No

What is the status of the establishment? Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment
(b) (6)

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

(b) (6)

Manufacturing Steps and/or Type of Testing
Manufacture of drug substance, Drug substance testing, Drug product testing

Is the site ready for inspection? Yes No N/A
If No, when will site be ready? (mm/dd/yyyy) _____

Add Second Continuation Page for #28

SECOND CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Pfizer Inc

Address 1 (Street address, P.O. box, company name c/o)

875 Chesterfield Parkway West

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Chesterfield

State/Province/Region

MO

Country

United States

ZIP or Postal Code

63017

Registration (FEI) Number

1940118

MF Number

Establishment DUNS Number

004954111

Is the establishment new to the application?

Yes No

What is the status of the establishment?

Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Drug substance testing, Drug product testing

Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Establishment Name

Pfizer Ireland Pharmaceuticals

Address 1 (Street address, P.O. box, company name c/o)

Grange Castle Business Park Clondalkin

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Dublin 22

State/Province/Region

N/A

Country

Ireland

ZIP or Postal Code

N/A

Registration (FEI) Number

3004145594

MF Number

Establishment DUNS Number

985586408

Is the establishment new to the application?

Yes No

What is the status of the establishment?

Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Drug product testing

Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Add Third Continuation Page for #28

THIRD CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name Hospira Zagrab Ltd.		Registration (FEI) Number 3010630287	
Address 1 (Street address, P.O. box, company name c/o) Prudnicka cesta 60		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 500625201	
City Prigorje	State/Province/Region Brdovecko		
Country Croatia	ZIP or Postal Code 10291		
Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	
<i>Establishment Contact Information at the site/facility</i>			
Name of Contact for the Establishment (b) (6)		Telephone Number (Include area code) (b) (6)	
(b) (6)		FAX Number (Include area code) (b) (6)	
(b) (6)		Email Address (b) (6)	
Manufacturing Steps and/or Type of Testing Drug Product Release Testing (Sterility)		Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____	
Establishment Name SGS Lab Simon SA		Registration (FEI) Number 3004186644	
Address 1 (Street address, P.O. box, company name c/o) Vieux Chemin du Poete 10		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 283063907	
City Wavre	State/Province/Region N/A		
Country Belgium	ZIP or Postal Code 1301		
Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	
<i>Establishment Contact Information at the site/facility</i>			
Name of Contact for the Establishment (b) (6)		Telephone Number (Include area code) (b) (6)	
(b) (6)		FAX Number (Include area code) (b) (6)	
(b) (6)		Email Address (b) (6)	
Manufacturing Steps and/or Type of Testing Drug Product Release Testing (Sterility)		Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____	
Add Fourth Continuation Page for #28			