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07/01/2022

code if applicable and area code) +49(0)61319084-390

4. Facsimile (FAX) Number (Include country

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

3. Telephone Number (Include country code if applicable and area code)

APPLICANT INFORMATION

+49 (0) 6131 9084-7593

2. Name of Applicant

BioNTech Manufacturing GmbH

Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2020 See PRA Statement on page 3.

1. Date of Submission (mm/dd/yyyy)

5.	Applicant Address						
	Address 1 (Street address, P.O. box, company name c/o)						Email Address
	An der Goldgrube 12						Ruben.Rizzi@biontech.de
	Address 2 (Apartment, suite, unit, building, floor, etc.)						Applicant DUNS
	City	State/P					117645848
	Mainz		N/A	-			U.S. License Number if previously issued
	Country			ZIP or Pos	stal Code		2229
6	Germany Authorized U.S. Agent (Required for non	-11 S an	nlicantel	55131			
0. /	Authorized U.S. Agent Name	-0.3. ap	plicarits)				Telephone Number (Include area code)
	Gosia Mineo, Director, Global Regulator	y Affair	s - Vaccin	nes			(b) (6)
		(b)	(6)				FAX Number (Include area code)
							,
							(b) (6) Email Address
							(b) (6) U.S. Agent DUNS
						ı	
PR	ODUCT DESCRIPTION	7. NDA 125742	-	or BLA Appli	cation Number		Supplement Number (If applicable)
a	 Established Name <i>(e.g., proper name, U</i>		_			45	
	OVID-19 mRNA Vaccine (nucleoside mo		iiv name)				
10.	Proprietary Name (Trade Name) (If any)					
	OMIRNATY						
	Chemical/Biochemical/Blood Product N OVID-19 Vaccine (BNT162, PF-0730204		any)				
_	Dosage Form	13. Strengths					14. Route of Administration
	quid	I .	30 mcg				Intramuscular
15	A. Proposed Indication for Use	•	- 1:	s this indicati	ion for a rare disease ((preva	alence <200,000 in U.S.)?
	tive immunization to prevent COVID-19 cause	d by					
SA	RS-CoV-2 in individuals ≥16 years of age		Does this product have an FDA Orphan Designation for this			D	yes, provide the Orphan esignation number for this
			i	ndication?		in	dication: Page for #15
45	O CNOMED OT Indication Disease. T	/11=-	41 - · · - 41		Yes No		
	3. SNOMED CT Indication Disease Term						
	T				drome coronavirus 2;	SAK	S-CoV-2 vaccination; COVID-19 vaccination
AF	PPLICATION INFORMATION		olication T elect one)		New Drug Application		
		,50			Abbreviated New Drug		
17.	If an NDA, identify the type 505(b)(1)	505 (b)(2)	18. If a BLA, identify	the t	type
	If a 351(k), identify the biological referen	nce prod	duct that i	s the basis f			
	ame of Biologic:				Holder of Licensed A		
	If an ANDA, or 505(b)(2), identify the lis	ted drug	g product	that is/are th			
	ame of Drug:				Application Number		
Ind	dicate Patent Certification: P1	□ P2		P3 🔲 F	P4 Section viii	i - MC	DU Statement of no relevant patents
FOI	RM FDA 356h (08/18 - PREVIOUS ED	ITIONS	S OBSOI	_ETE) I	Page 1 of 10		FDA-CBER-2022-58412-10316358801) 443-6740 EI

	Previous Page Nex	ct Page					
21.	Submission (See instructions) Product Correspondence	_	Labeling Suppler		CMC Supplement	✓ Efficacy Supplement	•
	Request for Proprietary Name		Other (Specify		arketing requirements of	John Million Co. S.,	Сероп
22.	Submission Sub-Type Presubmissio Initial Submis	_	Amendment Resubmission		23. If a supplement, ident the appropriate category	, I LARE I PROCADOR	oval (PA)
24.	For Originals and all Supplement combination product (21 CFR 3.2				oination Product (See instructions)	Request for Designation (RFD) Number	
25.	Does the submission contain: Only Pediatric data? Yes	✓ No Hu	ıman factors inform │Yes ✓ No	ation?	26. Proposed Marketing Prescription Prod	Status <i>(Select one)</i> uct (Rx) Over-The-Counter Prod	duct (OTC)
27.	Reasons for Submission						
						"Y in Individuals 12 Years of Age and Old	er
<u> — г</u>	Establishment Information (Full e Establishment Name	establishmen	t information shoul	d be p	rovided in the body of the	application.)	
	Pharmacia and Upjohn Company LLC	C (Pfizer)					
	Address 1 (Street address, P.O. bo	ox, company	name c/o)			Registration (FEI) Number	
	7000 Portage Road Address 2 (Apartment, suite, unit,	huilding floo	or etc.)			1810189	
	rtaarooo 2 (rtpararront, cane, arm,	banang, noc				MF Number	
	City Kalamazoo		State/Province/R MI	egion			
	Country		1	or Post	al Code	Establishment DUNS Number 618054084	
	USA		4900	1			
	Is the establishment new to the ap	oplication?	☐ Yes ✓ No		What is the status of the e	establishment? Active Inactive Without Without Inactive	Irawn
	Establishment Contact Informatio	n at the site	/facility				
	Name of Contact for the Establish	ment				Telephone Number (Include area co	de)
	(b) (6)	(k	o) (6)			(b) (6)	
П						FAX Number (Include area code)	
П						(b) (6)	
П						Email Address	
П							
П						(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? If No, when will site be ready? (mm/dd/yyyy)					N/A	
						Continuation Page for	28
29	Cross References (List related B	I As INDs 1	NDAs PMAs 510(k)s ID	Fs BMFs MAFs and DM	IFs referenced in the current applicat	
	D 19736, DMF 012683, DMF 9543, DM		•	•		• •	,
							Contin. Page for #29
30.	This application contains the follo	owing items	(Select all that app	ly)			
	1. Index 2. Labeling	g (Select on	e): 🔽 Draft Lab	eling	Final Printed Labeling	3. Summary (21 CFR 3	14.50 (c))
	4. Chemistry Section	B. Sample	s (21 CFR 314.50 ((e)(1);	ontrols information (e.g., 21 21 CFR 601.2 (a)) (Submit , 21 CFR 314.50(e)(2)(i); 2		
	5. Nonclinical pharmacology (e.g., 21 CFR 314.50(d)(2)	and toxicolo	gy section	, 5	6. Human pharmacol	kinetics and bioavailability section 50(d)(3); 21 CFR 601.2)	
	7. Clinical microbiology section	•				on (e.g., 21 CFR 314.50(d)(5); 21 CFF	R 601.2)
	Item 30 continued on page 3						

Previous Page Next Page							
30. This application contains the following items (Continued; select all th	at apply)						
9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	☐ 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)						
11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)						
13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c))	☐ 13. Patent information on any patent that claims the drug/ ☐ 14. A patent certification with respect to any patent that claims the						
15. Establishment description (21 CFR Part 600, if applicable)	☐ 16. Debarment certification (FD&C Act 306 (k)(1))						
17. Field copy certification (21 CFR 314.50 (I)(3))	18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)						
19. Financial Disclosure Information (21 CFR Part 54)							
20. Other (Specify): Revised USPI in response to FDA 29 June 2022 re	equest for replacement to date of PI for COMIRNATY in Individuals ≥ 12yo						
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 Gosia Mineo, Director, Global Regulatory Affairs - Vaccines	32. Date (mm/dd/yyyy) 07/01/2022						
33. Telephone Number (Include country 34. FAX Number (Include co	ountry code if 35. Email Address						
code if applicable and area code) (b) (6) (b) (6)	(b) (6)						
36. Address of Applicant's Responsible Official (b) (6)							
37. Signature of Applicant's Responsible Official or Other Authorized Official Other Authorized Official Digitally signed by Gosia Mineo DN: o=Pfizer Inc, cn=Gosia Mineo Date: 2022 07 01 10:12:11 -04'00'							
The information below applies only to require	ments of the Paperwork Reduction Act of 1995.						
The information below applies only to requirements of the Paperwork Reduction Act of 1995. The burden time for this collection of information is estimated to average 24 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right: Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov							
"An agency may not conduct or sponsor, and a person is not required to res collection of information unless it displays a currently valid OMB number."	pond to, a DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.						

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FIRST CONTINUATION PAGE FOR ITEM 28	Provide information for additional establishments below, as needed.					
Establishment Name Pfizer Manufacturing Belgium NV						
Address 1 (Street address, P.O. box, company	Registration (FEI) Number					
	Rijksweg 12					
Address 2 (Apartment, suite, unit, building, floo	Address 2 (Apartment, suite, unit, building, floor, etc.)					
City	State/Provin	nce/Region	l			
Puurs	N/A			Establishment DUNS Number		
Country Belgium		ZIP or Pos 2870	stal Code	370156507		
Is the establishment new to the application?		2870	What is the status of the	establishment?		
	Yes ✓	No	Pending	✓ Active ☐ Inactive ☐ Withdrawn		
Establishment Contact Information at the site.	/facility					
Name of Contact for the Establishment				Telephone Number (Include area code)		
(b) (6)) (6)			(1) (2)		
(L) (O)			(b) (6)		
			-	FAX Number (Include area code)		
				(b) (6)		
				Email Address		
				(b) (6)		
Manufacturing Steps and/or Type of Testing				Is the site ready Voc No No NA		
LNP production and bulk drug product formulation,	Fill and finish.	Primary pac	kaging Secondary	for inspection?		
packaging, Drug product testing	,		y	If No, when will site be ready? (mm/dd/yyyy)		
Establishment Name Wyeth BioPharma Division of Wyeth Pharmaceutic	ala I I C					
Address 1 (Street address, P.O. box, company				Registration (FEI) Number		
1 Burtt Road				1222181		
Address 2 (Apartment, suite, unit, building, floor	or, etc.)			MF Number		
07	01.1.10	. .		IMF Number		
City Andover	State/Provir	nce/Region				
Country	1,111	ZIP or Pos	stal Code	Establishment DUNS Number		
United States		01810		174350868		
Is the establishment new to the application?	Yes 🗸	No	What is the status of the e	establishment? 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)			(b) (6)		
				FAX Number (Include area code)		
				(b) (6)		
				Email Address		
				(b) (6)		
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A		
Manufacture of drug substance, Drug substance test	ing, Drug produ	ct testing		for inspection?		
				ready? (mm/dd/yyyy)		
				Add Second Continuation Page for #28		

Remove Continuation Page	ΙI	Return to Form	

SE	COND CONTINUATION PAGE FOR ITEM		Provide information for additional establishments below, as needed.			
	Establishment Name Pfizer Inc					
		II Da	aciatratica (FFI) Number			
	Address 1 (Street address, P.O. box, company		egistration (FEI) Number			
	875 Chesterfield Parkway West	19	940118			
	Address 2 (Apartment, suite, unit, building, floor, etc.)					F Number
	City					
	Chesterfield	MO	ince/Regior		Es	stablishment DUNS Number
	Country		ZIP or Pos	stal Code		
	United States		63017		00	4954111
	Is the establishment new to the application?	Yes ✓	☑ No	What is the status of t		blishment? Active Inactive Withdrawn
	t-				رت و	, teave massive vvianaraviii
	Establishment Contact Information at the site/	facility				
	Name of Contact for the Establishment				le	lephone Number (Include area code)
	(b) (6)	s) (6)				(1) (2)
	(L) (6)				(b) (6)
					FA	XX Number (Include area code)
						(b) (6)
					En	mail Address
						(1.) (0)
					L	(b) (6)
	Manufacturing Steps and/or Type of Testing					Is the site ready Yes No N/A
	Drug substance testing, Drug product testing					for inspection?
	S. 51					If No, when will site be ready? (mm/dd/yyyy)
					<u> </u>	
	Establishment Name					
	Establishment Name				·	
	Establishment Name Pfizer Ireland Pharmaceuticals					
		name c/o)			Re	egistration (FEI) Number
	Pfizer Ireland Pharmaceuticals	name c/o)				egistration (FEI) Number
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company				30	,
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo	or, etc.)	inco/Pogion		30	004145594
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo	or, etc.) State/Prov	ince/Regior	1	30 MF	004145594 F Number
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22	or, etc.)			30 MF	004145594
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country	or, etc.) State/Prov	ZIP or Pos		30 MF	004145594 F Number
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland	or, etc.) State/Prov		stal Code	30 MF	F Number stablishment DUNS Number
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application?	State/Prov	ZIP or Pos	stal Code What is the status of t	30 MF Es 98	F Number stablishment DUNS Number 5586408 blishment?
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application?	State/Prov N/A	ZIP or Pos	stal Code	30 MF Es 98	F Number stablishment DUNS Number
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/	State/Prov N/A	ZIP or Pos	stal Code What is the status of t	30 MF	F Number stablishment DUNS Number 5586408 blishment? Active
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment	State/Prov N/A	ZIP or Pos	stal Code What is the status of t	30 MF	F Number stablishment DUNS Number 5586408 blishment?
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A	ZIP or Pos	stal Code What is the status of t	30 MF	F Number Stablishment DUNS Number S586408 blishment? Active Inactive Withdrawn slephone Number (Include area code)
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	30 MF	F Number Stablishment DUNS Number S5586408 blishment? Active Inactive Withdrawn clephone Number (Include area code) (b) (6)
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	30 MF	F Number Stablishment DUNS Number S586408 blishment? Active Inactive Withdrawn slephone Number (Include area code)
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	30 MF	F Number Stablishment DUNS Number S5586408 blishment? Active Inactive Withdrawn clephone Number (Include area code) (b) (6)
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	30 MF Es 98 he estal g	F Number Stablishment DUNS Number SSS86408 blishment? Active Inactive Withdrawn slephone Number (Include area code) (b) (6) XX Number (Include area code)
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	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	and the state of t	F Number Stablishment DUNS Number S5586408 blishment? Active Inactive Withdrawn dephone Number (Include area code) (b) (6) XX Number (Include area code) (b) (6) Is the site ready Vas No No No
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6) (b)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	and the state of t	F Number stablishment DUNS Number stablishment DUNS Number stablishment DUNS Number stablishment? Active Inactive Withdrawn slephone Number (Include area code) (b) (6) XX Number (Include area code) (b) (6) Is the site ready Yes No N/A
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6) (b)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	and the state of t	F Number Stablishment DUNS Number S5586408 blishment? Active
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6) (b)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	and the state of t	F Number stablishment DUNS Number stablishment DUNS Number stablishment DUNS Number stablishment? Active Inactive Withdrawn slephone Number (Include area code) (b) (6) XX Number (Include area code) (b) (6) Is the site ready Yes No N/A
	Pfizer Ireland Pharmaceuticals Address 1 (Street address, P.O. box, company Grange Castle Business Park Clondalkin Address 2 (Apartment, suite, unit, building, floo City Dublin 22 Country Ireland Is the establishment new to the application? Establishment Contact Information at the site/ Name of Contact for the Establishment (b) (6) (b)	State/Prov N/A Yes	ZIP or Pos	stal Code What is the status of t	and the state of t	F Number Stablishment DUNS Number S5586408 blishment? Active

Remove Continuation Page		Return to Form
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HIRD CONTINUATION PAGE FOR ITEM 2	8 – Establis	hment Inf	ormation	Provide information for additional establishments below, as needed.
Establishment Name				
Hospira Zagrab Ltd.				
Address 1 (Street address, P.O. box, company	y name c/o)			Registration (FEI) Number
Prudnicka cesta 60				3010630287
Address 2 (Apartment, suite, unit, building, flo	or, etc.)			MF Number
0"	01 1 10 1	'D :		Wi Hambor
City		nce/Region		
Prigorje	Brdovecko	ZIP or Pos	atal Cada	Establishment DUNS Number
Country Croatia		10291	star Code	500625201
Is the establishment new to the application?		10271	What is the status of the	l establishment?
to the establishment new to the apphoalism.	☐ Yes 🗸	No	Pending	Active Inactive Withdrawn
Establishment Contact Information at the site	a/facility			
Name of Contact for the Establishment	, racinty			Telephone Number (Include area code)
(b) (6)				relephone Number (madde area code)
	(b) (6)			(b) (6)
	(-) (-)			
				FAX Number (Include area code)
				(b) (6)
				Email Address
				(b) (6)
				(b) (b)
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A
Drug Product Release Testing (Sterility)				for inspection?
=-126 1111				If No, when will site be
				ready? (mm/dd/yyyy)
Establishment Name				
SGS Lab Simon SA				
Address 1 (Street address, P.O. box, company	v name c/o)			Registration (FEI) Number
Vieux Chemin du Poete 10	,			3004186644
Address 2 (Apartment, suite, unit, building, flo-	or, etc.)			
				MF Number
City	State/Provi	nce/Region		
Wavre	N/A			Establishment DUNS Number
Country		ZIP or Pos	stal Code	283063907
Belgium		1301		
Is the establishment new to the application?		1	What is the status of the	
		No	Pending	Active Inactive Withdrawn
Establishment Contact Information at the site	e/facility			
Name of Contact for the Establishment				Telephone Number (Include area code)
(b) (6)	(I.). (2)			
((b) (6)			(b) (6)
				FAX Number (Include area code)
				(b) (6)
				Email Address
				(b) (6)
Manufacturing Of U. T. CT.				
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A for inspection?
Drug Product Release Testing (Sterility)				If No, when will site be
				ready? (mm/dd/yyyy)
				Add Fourth Continuation Page for #28
				Add Fourth Continuation Page for #28

FOURTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information	Provide information for additional establishments below, as needed.
Establishment Name Fresenius Kabi USA LLC	
(b) (4)	
Establishment Contact Information at the site/facility	
Name of Contact for the Establishment	Telephone Number (Include area code)
Anthony Giessert (b) (4), (b) (6)	47.49.47.69
(5) (4), (6) (6)	(b) (4), (b) (6)
	FAX Number (Include area code)
	N/A
	Email Address
	(b) (6)
Manufacturing Steps and/or Type of Testing	Is the site ready Yes No N/A for inspection?
manufacture, testing and release of diluent (0.9% Sodium chloride Injection, USP)	If No, when will site be ready? (mm/dd/yyyy)
	ready: (mm/dd/yyyy)
Establishment Name Hospira Inc.	
(b) (4)	
Establishment Contact Information at the site/facility Name of Contact for the Establishment	Telephone Number (Include area code)
Paul Lucas	leiephone Number (<i>include area code)</i>
(b) (4), (b) (6)	(b) (4), (b) (6)
	FAX Number (Include area code)
	(b) (4), (b) (6)
	Email Address
	(b) (6)
Manufacturing Steps and/or Type of Testing	
ivialitiacturing Steps and/or Type or Testing	Is the site ready Yes No N/A
manufacture, testing and release of diluent (0.9% Sodium chloride Injection, USP)	for inspection? If No, when will site be
	for inspection?

Remove Continuation Page	ΙI	Return to Form	

FIFTH CONTINUATION PAGE FOR ITEM 28	Provide information for additional establishments below, as needed.					
Establishment Name						
	BioNTech Manufactuing GmbH					
Address 1 (Street address, P.O. box, company Emil-von-Behring-Str. 76	Registration (FEI) Number 3011406957					
	Address 2 (Apartment, suite, unit, building, floor, etc.)					
	radiose 2 (ripartitions, date, dim, ballaring, nool, ote.)					
City	State/Provi	nce/Region				
Marburg	N/A	71D D	4-10-4-	Establishment DUNS Number		
Country Germany		ZIP or Pos 35041	stal Code	313270335		
Is the establishment new to the application?		33011	What is the status of the	establishment?		
	☐ Yes 🗸	No	Pending	Active Inactive Withdrawn		
Establishment Contact Information at the site	/facility					
Name of Contact for the Establishment				Telephone Number (Include area code)		
(b) (6)	h) (6)			(1.) (2)		
(b) (6)			(b) (6)		
				FAX Number (Include area code)		
				(b) (6)		
				Email Address		
				Linaii Address		
				(b) (6)		
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A		
Manufacture of drug substance, Drug substance tes	ting			for inspection?		
				If No, when will site be ready? (mm/dd/yyyy)		
				ready: (mm/dd/yyyy)		
Establishment Name						
Labor LS SE & Co KG				T		
Address 1 (Street address, P.O. box, company Mangelsfeld 4,5,6	/ name c/o)			Registration (FEI) Number		
Address 2 (Apartment, suite, unit, building, flo	or. etc.)			3002807481		
3,	,,			MF Number		
City	State/Provi	nce/Region				
Bad Bocklet				Establishment DUNS Number		
Country Germany		ZIP or Pos	stal Code	314929072		
Is the establishment new to the application?		7,700	What is the status of the	ı establishment?		
	☐ Yes 🗸] No		✓ Active ☐ Inactive ☐ Withdrawn		
Establishment Contact Information at the site	/facility					
Name of Contact for the Establishment				Telephone Number (Include area code)		
(b) (6)	b) (6)			(1.) (0)		
(1	J) (U)			(b) (6)		
				FAX Number (Include area code)		
				(b) (6)		
				Email Address		
				(b) (6)		
Manufacturing Steps and/or Type of Testing				Is the site ready Yes No N/A		
Drug substance testing (Bioburden)				for inspection?		
				If No, when will site be ready? (mm/dd/yyyy)		
				Add Sixth Continuation Page for #28		

Remove Continuation Page	ш	Return to Form	

SIXTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information					Provide information for additional establishments below, as needed.					
	Establishment Name BioNTech Innovative Manufacturing Services (BNT IMFS) GmbH									
-	Address 1 (Street address, P.O. box, company name c/o)					Registration (FEI) Number				
	Vollmersbachstrasse 66				3014049480	,				
	Address 2 (Apartment, suite, unit, building, floor, etc.)				MF Number					
-	City State/Province/Region									
	Idar-Oberstein					E LUCIA A BUNGAN A				
	Country		ZIP or Pos	stal Code		Establishment DUNS Number				
	Germany 55743				1 2	537365801				
	Is the establishment new to the application?	Yes	✓ No	What is the status o		ablishment? Active	Inactive		rawn	
	Establishment Contact Information at the site/I	facility								
-	Name of Contact for the Establishment				Т	elephone N	umber (Includ	de area cod	le)	
	(b) (6)						,		,	
	(b) (6)				(b) (6	3)			
					F		r (Include area	a code)		
							(, , , , ,		
						(b) (6	6)			
					E	mail Addres	 SS			
						(b)	(6)			
Ī	Manufacturing Steps and/or Type of Testing					Is the site		es 🗌 No	□ N/A	
	Drug substance testing					for inspect	ion?			
							n will site be m/dd/yyyy)			
	Establishment Name									
	Establishment Name BioNTech Manufacturing GmbH									
	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company	name c/o)				-	(FEI) Number			
	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube					Registration 015003158	(FEI) Number			
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company				3	015003158	(FEI) Numbei	-		
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor	r, etc.)	ingo/Dogion		3	-	(FEI) Numbei			
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor	r, etc.)	vince/Regior	1	3 N	015003158 1F Number				
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz	r, etc.)			3 N E	015003158 IF Number Establishme	(FEI) Number			
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor	r, etc.)	vince/Region ZIP or Pos		3 N E	015003158 1F Number				
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country	r, etc.)	ZIP or Pos		M E 3	015003158 MF Number Establishments 314382536	nt DUNS Num		rawn	
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application?	State/Prov	ZIP or Pos 55131	stal Code What is the status of	M E 3	015003158 MF Number stablishme 14382536 ablishment	nt DUNS Num	nber	rawn	
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fi	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estaing	015003158 AF Number Establishment 114382536 ablishment Active	nt DUNS Num	nber		
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/N Name of Contact for the Establishment	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estaing	015003158 AF Number Establishment 114382536 ablishment Active	nt DUNS Num	nber		
_	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fl Name of Contact for the Establishment Christoph Prinz	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estaing	015003158 AF Number stablishment 14382536 ablishment Active	nt DUNS Num Inactive umber (Include	nber		
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-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fl Name of Contact for the Establishment Christoph Prinz	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estaing	015003158 ### Number #### Stablishment* ### Active ### #### (b) (iii	nt DUNS Num Inactive umber (Include	□ Withdi		
	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fl Name of Contact for the Establishment Christoph Prinz	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estaing	015003158 AF Number Stablishment 14382536 ablishment Active Selephone N (b) (c)	nt DUNS Num Inactive umber (Include)	□ Withdi		
-	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fl Name of Contact for the Establishment Christoph Prinz	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estring \checkmark	015003158 AF Number Establishment and additional addi	Inactive Inactive Inactive (Include area	□ Withdi		
	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/fl Name of Contact for the Establishment Christoph Prinz	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estring \checkmark	015003158 AF Number Stablishment 14382536 ablishment Active Selephone N (b) (c)	Inactive Inactive Inactive (Include area	□ Withdi		
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	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/ft Name of Contact for the Establishment Christoph Prinz (b)	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estring \checkmark	olisoo3158 AF Number istablishment ablishment ablishment ablishment belephone N (b) (i) AX Number (b) (i) imail Addres (b) Is the site	Inactive Inactive Inactive Inactive Inactive	Withda with a code	le)	
	BioNTech Manufacturing GmbH Address 1 (Street address, P.O. box, company of An der Goldgrube Address 2 (Apartment, suite, unit, building, floor City Mainz Country Germany Is the establishment new to the application? Establishment Contact Information at the site/ft Name of Contact for the Establishment Christoph Prinz (b)	State/Prov	ZIP or Pos 55131	stal Code What is the status of	of the estring \checkmark	olisoosiis8 AF Number istablishment istabl	Inactive Inactive Umber (Include area (a) (b) (c) (c) (d) (e) (ready Ye) (f)	Withda with a code	le)	
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SEVENTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information			Provide information for additional establishments below, as needed.
Establishment Name Hospira, Inc			·
Address 1 (Street address, P.O. box, company r.	Registration (FEI) Number		
1776 North Centennial Drive			1925262
Address 2 (Apartment, suite, unit, building, floor,	MF Number		
City	State/Province/Region	 I	
McPherson	Kansas		Establishment DUNS Number
Country	ZIP or Pos	stal Code	
United States	030606222		
Is the establishment new to the application?	Yes 🗸 No	What is the status of Pendin	
Establishment Contact Information at the site/fa	acility		
Name of Contact for the Establishment			Telephone Number (Include area code)
Ian MacKellar			
(b)	(6)		(b) (6)
			FAX Number (Include area code)
			N/A
			Email Address
			(b) (6)
Manufacturing Steps and/or Type of Testing			Is the site ready Yes No N/A
Fill and finish, Primary packaging, Secondary packag	ing, Drug product testing		for inspection?
, , , , , , , , , , , , , , , , , , , ,	<i>c, c</i> ₁		If No, when will site be ready? (mm/dd/yyyy)
			Toddy: (mm/dd/yyyy)
Establishment Name Sandoz GmbH			
Sandoz Ginori		b) (4)	
	,	, , ,	
	1110		
Establishment Contact Information at the site/fa	acılıty		Tolophono Niverban (Institute anno anti-)
Name of Contact for the Establishment (b) (4), (b) (6)			Telephone Number (Include area code)
	, (b) (6)		(b) (4), (b) (6)
			FAX Number (Include area code)
	(b) (4), (b) (6)		
			Email Address
			(b) (4), (b) (6)
Manufacturing Steps and/or Type of Testing			Is the site ready Yes No N/A
(b) (4)			for inspection?
	If No, when will site be ready? (mm/dd/yyyy)		
			Add Eighth Continuation Page for #28
ORM FDA 356h (08/18 - PREVIOUS EDITION	S OBSOLETE)	Page10of 10	FDA-CBER-2022-5812-0163597 Remove Continuation Page Return to Form