

**EIR COVERSHEET**

08/26/2021

**Firm Information**

<b>FEI</b> 1000654629	<b>Firm Name</b> Pfizer Manufacturing Belgium NV	
<b>Firm Physical Address</b> Rijksweg 12, Puurs, BE	<b>Phone</b> (32)04778098 x00	<b>Profile Required</b> Yes
<b>Firm Mailing Address</b> Rijksweg 12, Puurs, BE	<b>Number of Employees</b> (b) (4)	<b>Establishment Size</b> (25,000,000-49,999,999)

**Responsible FDA Org**

Foreign - CBER (Non-Bioresearch Monitoring)

**Inspection Details**

<b>eNspect Operation ID</b> 201736	<b>Inspection Start Date</b> 06/24/2021	<b>Inspection End Date</b> 07/02/2021
<b>Inspection Basis</b> Surveillance	<b>Pre-Announced / Unannounced to Firm</b> Pre-Announced	<b>Days at the Facility</b> 7

**Endorsement**

PURPOSE: CBER conducted a Pre-License Inspection (PLI) from June 24 to July 2, 2021 of Pfizer Manufacturing Belgium NV (referred to as Pfizer Puurs) which is a formulation, filling, labeling and packaging facility located in Puurs, Belgium. The PLI was conducted for BLA STN 125742/0, COMIRNATY(COVID-19 Vaccine (BNT162b2, PF-07302048)), indicated for the prevention of COVID-19 in adults 16 years of age and older. Pfizer Puurs manufactures the BNT162b2 drug product, including the steps of Lipid Nanoparticle (LNP) (b) (4) Formulation bulk drug product, fill/finish, and labelling/packaging.

HISTORY: This facility has been previously inspected by FDA and the last inspection was a pre-approval inspection by ORA from Nov 09 to 16, 2017 for manufacturing of the NDA 20280 Supplement 91 for the Genotropin (somatropin) drug product. The facility is already approved as a multi-product facility to manufacture numerous CDER approved drugs.

CURRENT FINDINGS: No observations were noted during the PAI and no Form 483 was issued to Pfizer Puurs.

**ACTION:**

No further actions or follow-up are needed at this time.

**Products Covered**

Product Code	Establishment Type	Description	Additional Product Description
57 C H - 33	Manufacturer	COVID 19 Vaccine	BNT162b2 Drug product

**Inspected Processes & District Decisions**

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<b>PAC</b>	<b>Establishment Type</b>	<b>Process Code</b>	<b>Inspection Conclusions</b>
45848B	Manufacturer	57 C H -	No Action Indicated

<b>Final Decision</b>	<b>District Decision Made By</b>	<b>District Decision Date/Time</b>	<b>Decision Type</b>	<b>Follow-Up</b>
N	Fontan, Laura	08/21/2021 10:55 AM	No Action Indicated	

**Remarks**  
No 483 issued

<b>PAC</b>	<b>Establishment Type</b>	<b>Process Code</b>	<b>Inspection Conclusions</b>
45848B	Manufacturer	57 C H -	No Action Indicated

<b>Final Decision</b>	<b>District Decision Made By</b>	<b>District Decision Date/Time</b>	<b>Decision Type</b>	<b>Follow-Up</b>
Y	Peters, Lori	08/21/2021 06:50 PM	No Action Indicated	

**Remarks**

**Refusals**

No refusal

**Related Operations**

**FDA 483 Issued?** No

**Samples Collected**

**Recall Numbers**

**Related Consumer Complaints**

**Assignees Accomplishment Hours**

<b>Employee Name</b>	<b>Position Class</b>	<b>Hours Credited To</b>	<b>PAC</b>	<b>Establishment Type</b>	<b>Process</b>	<b>Hours</b>
Cheung, Anissa	FDA Center Employee	ORAHQ	45848B	Manufacturer	57 C H -	120
Fontan, Laura	FDA Center Employee	CBER	45848B	Manufacturer	57 C H -	120
Wu, Zhongren	Investigator	PHRM1	45848B	Manufacturer	57 C H -	120
Jackson, Susan	Investigator - Team Biologics	BIOL2	45848B	Manufacturer	57 C H -	120

**Total Hours** 480


**Endorsement Details**

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**Endorsing Supervisor Name**

Peters, Lori

Lori P.  
Peters -S

 Digitally signed by Lori P. Peters -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Lori P. Peters -S,  
0.9.2342.19200300.100.1.1=2000637691  
Date: 2021.08.26 13:35:05 -0400'

**Date and Time of Signature**

08/21/2021, 18:57:49 EDT

**Investigator Name**

Fontan, Laura

**Date and Time of Signature**

08/21/2021, 10:57:09 EDT