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

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Establishment Type</th>
<th>Description</th>
<th>Additional Product Description</th>
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<tbody>
<tr>
<td>57 C H - 33</td>
<td>Manufacturer</td>
<td>COVID 19 Vaccine</td>
<td>BNT162b2 Drug product</td>
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Inspected Processes & District Decisions
EIR COVERSHEET

PAC: 45848B
Establishment Type: Manufacturer

Process Code: 57 C H -
Inspection Conclusions: No Action Indicated

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

Remarks
No 483 issued

PAC: 45848B
Establishment Type: Manufacturer

Process Code: 57 C H -
Inspection Conclusions: No Action Indicated

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

Remarks

Refusals
No refusal

Related Operations

FDA 483 Issued? No

Samples Collected
Recall Numbers
Related Consumer Complaints

Assignees Accomplishment Hours

<table>
<thead>
<tr>
<th>Employee Name</th>
<th>Position Class</th>
<th>Hours Credited To</th>
<th>PAC</th>
<th>Establishment Type</th>
<th>Process</th>
<th>Hours</th>
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</thead>
<tbody>
<tr>
<td>Cheung, Anissa</td>
<td>FDA Center Employee</td>
<td>ORAIHQ</td>
<td>45848B</td>
<td>Manufacturer</td>
<td>57 C H -</td>
<td>120</td>
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<td>Fontan, Laura</td>
<td>FDA Center Employee</td>
<td>CBER</td>
<td>45848B</td>
<td>Manufacturer</td>
<td>57 C H -</td>
<td>120</td>
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<td>Wu, Zhongren</td>
<td>Investigator</td>
<td>PHRM1</td>
<td>45848B</td>
<td>Manufacturer</td>
<td>57 C H -</td>
<td>120</td>
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<td>Jackson, Susan</td>
<td>Investigator - Team Biologics</td>
<td>BIOL2</td>
<td>45848B</td>
<td>Manufacturer</td>
<td>57 C H -</td>
<td>120</td>
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Total Hours 480
Endorsement Details

**Endorsing Supervisor Name**

Peters, Lori

**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