DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

EIR COVERSHEET

08/26/2021

Firm Information

FEI
1222181

Firm Name
Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC

Firm Physical Address
1 Burtt Rd, Andover, MA, 01810-5901, US

Phone
1-978-475-9214

Profile Required
Yes

Firm Mailing Address
1 Burtt Rd, Andover, MA, 01810-5901, US

Number of Employees
(b) (4)

Establishment Size
(50,000,000- and over)

Responsible FDA Org
New England District Office

Inspection Details

eNSpect Operation ID
204656

Inspection Start Date
07/19/2021

Inspection End Date
07/23/2021

Inspection Basis
Surveillance

Pre-Announced / Unannounced to Firm
Pre-Announced

Days at the Facility
5

Endorsement
PURPOSE: CBER conducted a Pre-License Inspection (PLI) from July 19 to July 23, 2021, of Wyeth BioPharma Division of Wyeth Pharmaceuticals, LLC. (FEI#1222181) [referred to as Pfizer Andover], which is the drug substance manufacturing facility located in Andover, MA (USA). The PLI was conducted for original BLA STN 125742/0, COMIRNATY (COVID-19 mRNA Vaccine (BNT162b2, PF-07302048)), indicated for the prevention of COVID-19 in individuals 16 years of age and older. Pfizer Andover manufactures the BNT162b2 drug substance, including the steps of (b) (4) (b) (4)

HISTORY: This facility has been previously inspected by the FDA and the last inspection was a pre-approval inspection by CDER from April 29 to May 03, 2019, in support of CDER BLA 761118, Adalimumab (biosimilar to Humira). The facility is already approved as a multi-product facility to manufacture numerous FDA approved products.

CURRENT FINDINGS: The following thirteen objectionable conditions were noted during the PLI and issued to the Pfizer Andover on July 23,2021:
(1) insufficient data to support product quality prior to the release of a batch; (2) inadequate quality oversight; (3) deficient deviation investigations; (4,5) incomplete cleaning validation for specific equipment; (6) inadequate cleaning efficacy studies; (7) biological safety cabinets are not adequately monitored; (8) inadequate routine monitoring of the compressed air system; (9) the environmental program is deficient; (10) room status not adequately verified or documented; (11) standard operating procedures are not followed; (12) facility maintenance deficiencies; and (13) inadequate documentation of raw material storage.

ACTION: Recommend approval of original BLA STN 125742/0 based on Pfizers commitment to perform additional assessments and make timely corrections. The responses to the FDA Form 483 were adequate. (b) (5), (b) (7)(E) (b) (5), (b) (7)(E)

EIR COVERSHEET

08/26/2021

Products Covered

Product Code	Establishment Type	Description	Additional Product Description
57 C I - 33	Manufacturer	COVID 19 Vaccine	COVID-19 mRNA Vaccine (BNT162b2 Drug Substance)

Inspected Processes & District Decisions

PAC	Establishment Type	Process Code	Inspection Conclusions
45848B	Manufacturer	57 C I -	Correction Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
N	Jones, Kathleen	08/21/2021 10:37 AM	Voluntary Action Indicated	

Remarks

PAC	Establishment Type	Process Code	Inspection Conclusions
45848B	Manufacturer	57 C I -	Correction Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
Y	Peters, Lori	08/21/2021 10:12 PM	Voluntary Action Indicated	

Remarks

Refusals

No refusal

Related Operations

FDA 483 Issued? Yes

Samples Collected	Recall Numbers	Related Consumer Complaints

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Jones, Kathleen	FDA Center Employee	CBER	45848B	Manufacturer	57 C I -	290
Allen, Ekaterina	FDA Center Employee	CBER	45848B	Manufacturer	57 C I -	250

EIR COVERSHEET

08/26/2021

Cheung, Anissa	FDA Center Employee	ORAHQ	45848B	Manufacturer	57 C I -	80
Emerson, Debra	Investigator - Team Biologics	BIOL1	45848B	Manufacturer	57 C I -	160

Total Hours 780

Endorsement Details

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=2000437691
Date: 2021.08.26 13:26:52 -04'00'

Date and Time of Signature
08/21/2021, 22:21:10 EDT

Investigator Name
Jones, Kathleen

Date and Time of Signature
08/21/2021, 10:31:17 EDT