EIR COVERSHEET

01/28/2022

Firm Information

FEI
3015047170

Firm Name
Aldevron LLC

Firm Physical Address
4055 41st Ave S, Fargo, ND, 58104-7869, US

Phone
1-701-297-9256

Profile Required
No

Firm Mailing Address
4055 41st Ave S, Fargo, ND, 58104-7869, US

Number of Employees

Establishment Size
(Unknown)

Responsible FDA Org
Division of Blood Components and Devices

Inspection Details

eNSpect Operation ID
214691

Inspection Start Date
11/01/2021

Inspection End Date
11/05/2021

Inspection Basis
Surveillance

Pre-Announced / Unannounced to Firm
Pre-Announced

Days at the Facility
5

Endorsement
CBER performed a PLI, under Modernas rolling BLA (STN 125752/0) for SPIKEVAX (COVID-19 Vaccine, mRNA), of Aldevron, LLC, Fargo, ND (FEI No. 3015047170), from November 1 to 5, 2021. Aldevron is a CMO that produces linearized pDNA for use in the manufacture of SPIKEVAX DS.
The current PLI was the first FDA inspection of Aldevron, LLC.
The scope of the PLI focused on the Quality, Production, Facilities and Equipment, Materials, Packaging and Labeling, and Laboratory Control systems. Records reviewed included, but were not limited to, the following: quality event (QE) investigations; batch production records; CAPA plans; change requests; changeover procedures; cleaning and sanitization procedures; equipment logbooks; equipment cleaning validations; facility and equipment qualifications; environmental monitoring (EM) procedures and trend reports; gowning certification procedures and results; (b) (4) simulation reports and batch records; Quality Unit policies and procedures; training records; in-process testing/controls; and related procedures, policies and/or protocols.
The following operations were also observed: visual inspection of starting material ((b) (4) from Moderna); upstream activities ((b) (4)) for Lot No. (b) (4) ; downstream activities ((b) (4)) for Lot No. (b) (4) ; and (b) (4) of Lot No. (b) (4) .
No inspectional observations were issued at the conclusion of the inspection; however, the following discussion items were reviewed with management during the closeout meeting:
Gowning Procedures and Background Environments for Execution of Certain Upstream Activities
Quality Management System (QMS) Enhancements
Controlled Issuance of Documents and Forms
Dedicated Production Area for Moderna Products
Installation of (b) (4)
Security and Access to QI and Warehouse Freezers
Mold Excursions
Mold Specifications

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Categorization of Quality Events
The firm acknowledged the discussion items and agreed to address any associated recommendations.

Products Covered

Product Code	Establishment Type	Description	Additional Product Description
57 C I - 33	Manufacturer	COVID 19 Vaccine	Linearized plasmid DNA (pDNA)

Inspected Processes & District Decisions

PAC	Establishment Type	Process Code	Inspection Conclusions
45848B	Manufacturer	57 C I -	No Action Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
N	Lynch, Christian	01/28/2022 11:14 AM	No Action Indicated	Refer to Center

Remarks

PAC	Establishment Type	Process Code	Inspection Conclusions
45848B	Manufacturer	57 C I -	No Action Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
Y	Lorenzo, Anthony	01/28/2022 01:13 PM	No Action Indicated	

Remarks

Refusals

No refusal

Related Operations

FDA 483 Issued? No

Samples Collected	Recall Numbers	Related Consumer Complaints

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours

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Raju, Prabhu	Investigator	BIOL1	45848B	Manufacturer	57 C I -	110
Lynch, Christian	FDA Center Employee	ORAHQ	45848B	Manufacturer	57 C I -	225
Greenleaf, Jared	FDA Center Employee	CBER	45848B	Manufacturer	57 C I -	50

Total Hours 385

Endorsement Details

Endorsing Supervisor Name

Date and Time of Signature

Investigator Name
Lynch, Christian

Date and Time of Signature
01/28/2022, 11:08:04 EST