

EIR COVERSHEET

01/31/2022

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; aseptic process 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) Software

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
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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**

Lorenzo, Anthony

Date and Time of Signature

01/28/2022, 17:24:24 EST

Investigator Name

Lynch, Christian

Pankaj H. Amin -S

Digitally signed by Pankaj H.
Amin -S
Date: 2022.01.31 11:59:20 -05'00'

Date and Time of Signature

01/28/2022, 11:08:04 EST