DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. FDA CBER Office of Compliance and Biologics Quality Building 71, Room 5054, 1093 New Hampshire Avenue Silver Spring, MD 20993-0002 TEL: (240) 402-8914 Industry Information: www.fda.gov/oc/industry	January 26 - February 03, 2023
	FEI NUMBER 3010165220

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Frings, Vice President & Site Head, Managing Director

FIRM NAME	STREET ADDRESS
Dynavax GmbH	Eichsfelder Strasse 11
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
40595 Dusseldorf, Germany	Bulk Drug Substance Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED

OBSERVATION 1

The investigation into the out of specification test result and the corresponding manufacturing investigation were inadequate in that the investigation did not extend into the review of the (b) (4) sanitization of the (b) (4). Specifically,
Laboratory investigation #0202-001 and deviation DEV-00031 were initiated on March 16, 2020, for an OOS endotoxin result for the (b) (4). The investigation root cause was assigned to method due to interference with (b) (4) in the test sample. The manufacturing investigation failed to evaluate the (b) (4) sanitization cycle of the (b) (4). Additionally, the periodic re-qualification of the (b) (4) sanitization of the (b) (4) was not reviewed as part of the investigation.

Feb 3, 2023

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Susan Jackson	Susan Jackson, CSO	Feb 03, 2023