DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	8/21/2023-8/29/2023*
	FEI NUMBER 3013514411

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tim Pöpken, Managing Director

FIRM NAME	STREET ADDRESS
Burgwedel Biotech GmbH	Im Langen Felde 5
CITY, STATE, ZIP CODE, COUNTRY Burgwedel, Lower Saxony, 30938 Germany	TYPE ESTABLISHMENT INSPECTED Biologics Vaccine Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Deviations from written sampling plans, test procedures and laboratory mechanisms are not justified.

Specifically,

There is a failure to thoroughly review any unexplained discrepancy from the firm's contract testing lab used for stability studies of ERVEBO drug product vaccine and related materials. For example, the contract testing lab (b) (4) in (b) (4) is used to perform stability studies for ERVEBO vaccine (recombinant vesicular stomatitis virus-Zaire Ebola live attenuated virus). From 2019-2023, there were 7 out of 18 stability deviations from this contract testing lab for different reasons including missed stability time point; use of expired media for cell potency assay; sample mismanagement; incorrect temperature sample storage during testing; and other reasons. The firm has not fully investigated these deviations to ensure that the contract testing lab is managing the stability samples and performing the stability testing correctly.

***DATES OF INSPECTION**

8/21/2023(Mon), 8/22/2023(Tue), 8/23/2023(Wed), 8/24/2023(Thu), 8/25/2023(Fri), 8/28/2023(Mon), 8/29/2023(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, Investigator - Team Biologics Laurel A Beer, Investigator X Roger F Zabinski Investigator - Team Biologics Signed By: Roger F. Zabinski -S Date Signed: 08-29-2023 15:39:38	8/29/2023

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X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 08-29-2023 15:40:13

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Roger F Zabinski, Investigator - Team Biologics
Laurel A Beer, Investigator

X Roger F Zabinski
Investigator - Team Biologics
Signed By: Roger F. Zabinski -S
Date Signed: 08-29-2023
15:39:38

DATE ISSUED
8/29/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."