DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	4/15/2024-4/18/2024
	FEI NUMBER 3003098680

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Niklas H. Schier, Site Head

FIRM NAME	STREET ADDRESS
CSL Behring GmbH	Emil-Von-Behring-Str. 76
CITY, STATE, ZIP CODE, COUNTRY Marburg, Hassia, 35041 Germany	TYPE ESTABLISHMENT INSPECTED Biologics & Medical Device 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, you have not fully documented and implemented written procedures for analysis of complaints to identify existing and potential quality problems. For example,

A. You have not fully implemented Section 4.7 of your Complaints Management procedure requiring that you document the justification as to whether or not additional actions are required following your analysis to determine if there is a trend in the compliant data.

B. You do not have written procedures defining your monthly complaint data trend analysis and evaluation. Further, your records of trend analysis for complaint data in December 2023, January 2024, and February 2024 do not list an evaluation covering Alert Limit deviations which were identified during these reviews.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joshua J Silvestri, Investigator	X Joshua J Silvestri Investigator Signed By: Joshua J. Silvestri -S Date Signed: 04-18-2024 12:13:18	4/18/2024

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Annotations to Observations

Observation 1: Not annotated

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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."