

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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| DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715 | DATE(S) OF INSPECTION 4/15/2024-4/18/2024 FEI NUMBER 3003098680 |
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Niklas H. Schier, Site Head

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| FIRM NAME CSL Behring GmbH | STREET ADDRESS Emil-Von-Behring-Str. 76 |
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| CITY, STATE, ZIP CODE, COUNTRY Marburg, Hattia, 35041 Germany | TYPE ESTABLISHMENT INSPECTED Biologics & Medical Device Manufacturer |
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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 (b) (4) complaint data trend analysis and evaluation. Further, your records of trend analysis for complaint data in (b) (4) (b) (4) do not list an evaluation covering Alert Limit deviations which were identified during these reviews.

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

Observation 1: Not annotated

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