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	4/28/2025-5/2/2025* FEI NUMBER 4439

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Karin Gremminger-Trommer, CEO	
FIRM NAME	**STREET ADDRESS**
August Reuchlen GmbH	Junkerstr. 8
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Tuttlingen, Baden-Wurttemberg, 78532 Germany	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

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, the following CAPAs were not adequately documented:

CAPA 2024-006
CAPA 2024-007
CAPA 2024-008
CAPA 2023-001

OBSERVATION 2

The type and extent of control to be exercised over services and consultants was not clearly defined.

Specifically, the firm's supplier controls procedures do not adequately establish the type and extent of control to be exercised over some contractors, and consultants, based on the evaluation results.

*DATES OF INSPECTION

4/28/2025(Mon), 4/29/2025(Tue), 4/30/2025(Wed), 5/02/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	John A Sciacchitano, Investigator - Dedicated Device Cadre	X John A Sciacchitano Investigator - Dedicated Device Cadre Signed By: John Sciacchitano -S Date Signed: 05-02-2025 10:13:34	5/2/2025

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Annotations to Observations

Observation 1:

Observation 2:

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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."