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	2/13/2023-2/16/2023
	FEI NUMBER 3004035727

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin Rauer, General Manager

FIRM NAME	STREET ADDRESS
Bernd Richter GmbH	Hansestr. 4
CITY, STATE, ZIP CODE, COUNTRY Wipperfurth, North Rhine-Westphalia, 51688 Germany	TYPE ESTABLISHMENT INSPECTED 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 monitoring and control of process parameters for a validated process have not been adequately established.

Specifically,

Your firm failed to provide documentation for the validation of crimping machine SN [redacted] during this inspection.

OBSERVATION 2

Procedures for the acceptance of in-process product have not been adequately established.

Specifically,

Your firm failed to adequately define, document, and implement your procedures for in-process testing. For example, your procedure for verifying the crimping process specifies the need to measure the [redacted] needed to remove the crimps from [redacted] samples to ensure the crimp is acceptable. Your documentation shows your firm has only tested [redacted] samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tiki Dixon, Investigator X Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 02-16-2023 10:02:09	2/16/2023

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X Tiki Dixon
Investigator
Signed By: 2000441527
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiki Dixon, Investigator	DATE ISSUED 2/16/2023

X Tiki Dixon
Investigator
Signed By: 2000441527
Date Signed: 02-16-2023
10:02:09

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."