DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	3/12/2025-3/13/2025
	FEI NUMBER 3009631939

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John M. Lacheta, Director, Quality Assurance

FIRM NAME	STREET ADDRESS
Red Star Contract Manufacturing, Inc.	1560 N State Road 5
CITY, STATE, ZIP CODE, COUNTRY Larwill, IN 46764-9791	TYPE ESTABLISHMENT INSPECTED HCT/P Distributor

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 I OBSERVED:

OBSERVATION 1

Storage areas and stock rooms were not controlled to prevent mix-ups, contamination and cross contamination of HCT/Ps, supplies and reagents and to prevent HCT/Ps from improperly being made available for distribution.

Specifically,

Your firm has not established a standard operating procedure regarding quarantine of HCT/P products. This includes for returned products from customers and unacceptable incoming product from the manufacturer.

OBSERVATION 2

Recorded storage temperatures were not periodically reviewed to ensure that temperatures have been within acceptable limits.

Specifically,

During review of records on 03/12/2025, documentation of temperature record review was unavailable. Your firm receives, stores and distributes ambient temperature HCT/P products. Your firm representative stated temperatures are not reviewed unless an alarm is received.

You began using this temperature monitoring system on August 29th, 2019. The temperature range of your probes were set outside of the HCT/Ps manufacturer's requirement of 15-30 C. Since 2018, you

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Gabryelle J Solverud, Investigator X Gabryelle J Solverud Investigator Signed By: Gabryelle J. Solverud - S Date Signed: 03-13-2025 14:16:34	3/13/2025

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have received stored and distributed approximately (b) (4) HCT/P bone products.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gabryelle J Solverud, Investigator

X Gabryelle J Solverud
Investigator
Signed By: Gabryelle J. Solverud - S
Date Signed: 03-13-2025 14:16:34

DATE ISSUED
3/13/2025

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."