DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	6/16/2025-6/25/2025* FEI NUMBER 3003302546

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott T. Unterbrunner, Plant Manager

FIRM NAME	STREET ADDRESS
Sterling Technology, LLC	133 32nd Ave S
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brookings, SD 57006-4719	Bovine Colostrum 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

You did not establish product specifications for identity, purity, strength, composition and limits on contamination.

Specifically, you manufacture shelf stable, (b) (4), bovine (b) (4) colostrum for (b) (4) in unflavored and flavored varieties which you fill into the final packing which consists of (b) (4) and (b) (4) bottles fitted with a (b) (4) (b) (4) and (b) (4). You ship the finished products unlabeled to your customer who labels it as (b) (4) (b) (4). You have no contract, quality agreement, or labeling agreement with (b) (4) and were unable to provide finished product specifications. The product receives (b) (4) treatments during the process at (b) (4) for at least (b) (4) after which the product passes through a (b) (4) as a part of the manufacturing process for (b) (4) (b) (4), again when transferring the finished product into the (b) (4) tank, and lastly at finished container filling. The finished product pH is adjusted to (b) (4) using (b) (4) after the initial (b) (4). You were unable to provide validation as to how the process renders this shelf-stable product safe from bacterial growth and/or toxin formation.

OBSERVATION 2

For component(s) used in the manufacture of a dietary supplement, you did not establish identity specifications, necessary specifications to ensure the specifications for purity, strength, and composition of the dietary supplement are met and limits on contamination to ensure the quality of the dietary supplement.

Specifically, you manufacture shelf stable, (b) (4), bovine (b) (4) colostrum for (b) (4) in unflavored and flavored varieties which you fill into the final packing which consists of (b) (4) and (b) (4) bottles fitted with a (b) (4) (b) (4) and (b) (4). You ship the finished products unlabeled to your customer who labels it as (b) (4). You have no contract, quality agreement, or labeling agreement with (b) (4), and you stated having no knowledge of the contents of the (b) (4) which (b) (4) provides you for incorporation into the (b) (4) batches as the components are not labeled to declare their contents. You were unable to provide component specifications.

OBSERVATION 3

You did not establish packaging specifications.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Darren D Holaday, Investigator Robert J Waldorf, Investigator	X Darren D Holaday Investigator Signed By: Darren D. Holaday -S Date Signed: 06-25-2025 11:39:21	6/25/2025

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***DATES OF INSPECTION**
6/16/2025(Mon), 6/17/2025(Tue), 6/18/2025(Wed), 6/25/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darren D Holaday, Investigator Robert J Waldorf, Investigator X Darren D Holaday Investigator Signed By: Darren D. Holaday -S Date Signed: 06-25-2025 11:39:21	6/25/2025

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."