DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/28/2026-4/30/2026 FEI NUMBER 1047134

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cori D. Capik, CEO & President

FIRM NAME	STREET ADDRESS
Continental Services Group, Inc.	2901 W Broward Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ft Lauderdale, FL 33312-1249	Blood Bank

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

Written reports of investigations of adverse reactions, including conclusions and follow up, are not prepared and maintained.

Specifically,

1. Donor [redacted] experienced a donor reaction after donating whole blood on [redacted]. The donor reaction report describes the reaction as "severe," in which paramedics were called to assist the donor. While reviewing the DR-018 (Rev 6) Donor Reaction Report for this event, we noted that the establishment did not followed-up with the donor per SOP DR-018 Adverse Donor Reactions (Rev 6), Attachment 2, which states that after a severe reaction: "A representative from CSG will be contacting you to follow-up".
2. While reviewing DR-018 Donor Reaction Reports (Rev 6), we noticed 5 out of 24 reports/instances dating from [redacted] (b)(4) in which the reports do not contain the classification of the reaction (severe or not severe). There was no formal assessment of the criticality of the donors' reactions, and SOP DR-018 Adverse Donor Reactions (Rev 6) was not followed.

OBSERVATION 2

Failure to store all supplies and reagents used in the collection and processing of blood and blood components in a safe, sanitary and orderly manner.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ivan E Reyes, Investigator Sergio E Delgado, Investigator	X Ivan E Reyes Investigator Signed By: 2000357185 Date Signed: 04-30-2026 12:55:37	4/30/2026

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Specifically,

- On April 30, 2026, during the walk through of the storage room containing released and available-for-use [redacted] supplies, [redacted] of expired [redacted] were observed co-located with current inventory:
  - [redacted] containing
  - [redacted] containing (b)(4)

  These expired supplies were not segregated, quarantined, or clearly identified as expired, creating a risk of inadvertent use in blood collection or processing operations.
- SOP [redacted]-001 – Receipt, Inspection and Release of Materials (Rev 5), Section III - Definitions, Page 2, speaks about segregation of areas within the [redacted] including a "[redacted]" area and a "[redacted]" area. Currently, there are no designated/segregated areas within the [redacted] supply storage room clearly defined as such, creating a risk of inadvertent use in blood collection or processing operations.

X Sergio E Delgado
Investigator
Signed By: 2003068147
Date Signed: 04-30-2026 12:56:13

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ivan E Reyes, Investigator Sergio E Delgado, Investigator	X Ivan E Reyes Investigator Signed By: 2000357185 Date Signed: 04-30-2026 12:55:37	4/30/2026

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."