DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	3/25/2026-6/3/2026*
	FEI NUMBER 3001451489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Francis S. Kim, Senior Vice President of North America Quality and Quality Operations

FIRM NAME	STREET ADDRESS
Fresenius Medical Care Renal Therapies Group, LLC	920 Winter St Bld 920
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waltham, MA 02451-1521	Manufcaturer

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 WE OBSERVED:

OBSERVATION 1

Records of risk management activities in product realization were not adequately maintained.

Specifically,

A. Your firm's Risk/Hazard Analysis Procedure S100429-02, Rev. L, Effective 03/30/2026 does not define a numerical value for probability when harm cannot be confirmed. Instead a probability of zero is assigned, which excludes known events from risk reassessment. Periodic Risk Review RSK-0000360210 (October 2024–September 2025) documents 21 reportable events, 6 (b) (4) (Severe), 4 (b) (4) (Critical), and 11 (b) (4) (Fatal) that were all assigned a probability of zero despite confirmed occurrences. These were excluded from probability calculations because harm could not be directly attributed to the device or because insufficient information was available, despite determining that they could have caused or contributed to a death or serious injury. Specifically:

   I. The complaint list used during this review identified 95 ultrafiltration (UF) pump failure complaints, including a complaint associated with death # (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C) in which post-event testing confirmed the UF pump was out-of-specification. The complaint was assigned zero harm and excluded from probability calculations alongside the remaining 94 UF-related complaints.

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	Sunita Pandey, Investigator Thomas Siebertz, Investigator	X Sunita Pandey Investigator Signed By: 2003030873 Date Signed: 06-03-2026 16:24:21	6/3/2026

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II. No updates to occurrence probability or severity were made to the 2008T HD System Risk/Hazard Analysis (508152, Rev. T) as a result of this review.

III. Your firm's hazard analysis identifies hypotension as an associated harm from UF malfunction at (b) (4) severity; however, complaint (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C) was closed as unconfirmed without product return, and no risk analysis updates were made despite (b) (6), (b) (7)(C) identifying apparent death (b) (4) from hypotension and had UF pump out-of-specification.

IV. Your firm identified 463 potentially use-related complaints during this review yet concluded "NO" to unforeseen misuse, inconsistent with the documented pattern of contraindicated use in patients below 20 kg identified in the firm's complaint records.

B. Your firm's Instructions for Use (IFU) for 2008 series hemodialysis machines contain instructions for using third-party reusable dialyzer, however your firm did not address potential hazards for this indicated use in your hazard analysis. The only validation for use of third-party dialyzers with the 2008 series Hemodialysis Machine performed was validation of the dimensions and fitment with the machine. This does not ensure the machine is safe and effective for use under all indicated operating conditions.

C. S100429-01 (Safety Risk Management, Rev. P), Section 4.4.2.3 and Appendix A require that severity be estimated based on the worst-case harm that can result from the hazardous situation using medical/clinical expertise; however, your firm failed to apply this requirement consistently across CAPA 2115182, initiated on 05/30/2025 for Combiset Bloodlines used with the 2008 series hemodialysis machines manufactured by your firm, and CAPA 2016752, initiated on 02/24/2025 for 5008X Bloodlines used with hemodialysis machines manufactured by your firm's sister company. For CAPA 2016752, the firm applied the worst-case potential harm of (b) (4) (Fatal/Death) for blood leaks to estimate event risk as required by S100429-01, resulting in (b) (4) (Medium Risk); whereas for CAPA 2115182, your firm used only the highest harm actually

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observed in complaints (b) (4) and further calculated probability independently for each observed severity level using only 1 confirmed (b) (4) complaint as the numerator without considering that the 31 (b) (4) blood loss complaints represented the same hazardous situation already confirmed to result in (b) (4) harm resulting in an event risk of (b) (4) (Low Risk). As a result of this inconsistent application of S100429-01, 5008X Bloodlines were subject to a Class II recall, RES 96827 which removed all the affected products based on only 7 complaints received from 10/20/2024 to 03/20/2026 all graded at (b) (4) severity, while no field action was initiated for Combiset Bloodlines despite 106 complaints across multiple lots, multiple consignees, and confirmed (b) (4) patient harm.

OBSERVATION 2

Design and development verification plans were not adequately documented.

Specifically,

A. Your firm's Design Verification Procedure, S100021-12, Rev M, Effective 08/28/2025, Section 4.1.1 defines design verification as the process of obtaining objective evidence that the design output meets the design requirements (Engineering Inputs); however, your firm failed to adequately verify the design of the UF pump accuracy and alarm system.

   I. EI78953, EI78954, and EI78955, which establish UF pump alarm conditions serving as the primary PMD (Protective Measure by Design) safety mechanisms for 2008 T Hemodialysis Machines identified in 2008T HD System Risk/Hazard Analysis, 508152, Rev T, to prevent patient harm from inaccurate ultrafiltration delivery, were not adequately verified or validated, as the verification testing, VAL0747R-04, also provided as the validation testing failed to confirm that these alarms trigger under actual clinical use conditions. As a result, there is no objective evidence that these safety mechanisms can detect the UF pump failure modes documented in complaints (b) (6), (b) (7)(C) received on (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) received on (b) (6), (b) (7)(C) associated with death. In both

complaints, the UF pump stroke volume was out of specification, and no alarms or safety mechanisms were triggered.

II. Your firm failed to provide objective evidence that the design input requirement established in EI46675 for the Ultra Filtration (UF)/Fluid Removal Accuracy of the 2008T HD Machine, as specified in design trace matrix (b) (4), Revision BI, Effective 03/19/2026, which requires UF Pump 22 to deliver (b) (4) per stroke when outlet pressure is between (b) and (b) (4) psi, has been fulfilled.

B. Your firm failed to demonstrate that the 2008 series Hemodialysis Machines meets the requirement of at least (b) (4) useful life per requirements in Design Verification Procedure, S100021-12, Rev M, as follows:

I. Your firm's last full system-level reliability verification testing for 2008 series HD Machines including 2008K2, 2008 K@ Home and 2008 T supporting the (b) (4) useful life claim was completed in 2014 (VAL 0030). Since that time, your firm made several design changes that could affect the outcome of that testing including the (b) (4) Tubing Change (VAL 113 R1, 2022) which replaced all hydraulic tubing in the device. No justification is provided to support lack of re-verification of the useful life of the device. In addition, per VAL113R1, verification testing was conducted only on test fixtures, not on actual production machines.

II. VAL 0030R, Rev A (2014) and VAL 1113 R1, Rev A (2022) tested reliability of components through accelerated use simulations to verify the (b) (4) useful life by applying a (b) (4) statistical model in order to reduce the required sample size from (b) (4) to (b) (4) samples and permitted abbreviated test cycles to substitute for full-duration cycles. Adequate rationale was not documented to support this. Silicone tubing, a primary subject of VAL 1113 R1, exhibits a wear-out failure mode characterized by time-dependent degradation and an increasing hazard rate, which is incompatible with the

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constant hazard rate assumption of the (b) (4) model as applied. Neither VAL 0030 nor VAL 1113 R1 evaluates device or component performance beyond the (b) (4) threshold, and your firm do not provide decommissioning procedures to users. At least one complaint resulting in a death (Complaint #(b) (6), (b) (7)(C), dated(b) (6), (b) (7)(C)) was reviewed which involved a machine that was over 9 years old at the time of the event; however, your firm failed to consider device age during their complaint investigation.

C. Reliability testing in VAL 1113 R1 (2022) for silicone tubing components subject to thermal and chemical stress does not reflect actual field use conditions, contrary to Section 4.5.6, of Design Verification Procedure, S100021-12, Rev M, Effective 08/28/2025 which requires that verification protocols define challenge conditions, specific conditions and stimuli for each verification item, and test environment conditions specified as a range or nominal value with tolerance in the following respects:

I. The test protocol does not define the flow rate used in the test fixture, despite the IFU specifying a maximum flow rate of(b) (4) mL/min.

II. The IFU specifies heat disinfection duration can be set from (b) (4). The protocol states a default(b) (4) cycle was used during the testing; however test records do not document the actual duration of each disinfection cycle. In addition, no justification is provided for how this simulates real world or worst-case conditions.

III. Test records indicate cycles were paused to replace (b) (4) a condition that does not reflect actual clinical use.

IV. The mandatory rinse cycle (b) (4)) required after chemical dwells with Formaldehyde and recommended after each treatment ((b) (4)) was entirely omitted from the

protocol.

V. VAL 0030 (2014) and VAL 113 R1 (2022) were identified as the supporting testing for the preventive maintenance requirement to rebuild UF, concentrate (b) (4) and bicarbonate pumps every (b) (4) or (b) (4) hours on 2008T machines, as required by Preventive Maintenance Procedures P/N 508033, P/N 507297, Rev. L, and P/N 508138. Neither study tested whether these pumps can reliably maintain functionality for the full (b) (4) or (b) (4) interval.

D. Verification testing report VAL0261R, dated 11/05/2015, was provided as the only documented testing performed to support the DIASAFE plus filter can produce ultra-pure dialysate when used with the 2008T Machines. The DIASAFE plus filter serves as a critical safety barrier in the dialysate fluid path, functioning to reduce levels of bacteria and endotoxin (pyrogenic material) in the dialysate to achieve ultrapure dialysis fluid quality. However, the verification testing documented in VAL0261R was conducted exclusively on the 2008K and 2008K2 hemodialysis machines and was not performed on the 2008T series hemodialysis machines, including their current configuration without any documented rationale to support the applicability of the 2008K and 2008K2 verification results to the 2008T platform.

OBSERVATION 3
Design and development validation was not adequately completed prior to release for use of the product to the customer.

Specifically,

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Design and development validation was not adequately followed to demonstrate that the 2008 Series Hemodialysis Machine meets its safety and performance specifications and intended use under defined actual or simulated use conditions, as required by Design Validation Procedure S100021-13, Rev. L, Effective 06/16/2025.

A. The Operator's Manuals for the 2008 Series Hemodialysis Machines (2008K, P/N 490042 Rev P; 2008K2, P/N 490136 Rev K; and 2008T, P/N 490122 Rev AE) each state that the respective devices are compatible with commercially available third-party reusable dialyzers. However, your firm could not provide validation data to support the use of 2008 Series Hemodialysis Machines when used with third-party reusable dialyzers.

B. The (b) (4) Disinfection Validation, VAL1133P3, Rev B was conducted to demonstrate removal of (b) (4) from the internal hydraulic circuit of 2008 K2, 2008 K @ home and 2008T series however, the validation testing failed to achieve its stated objectives of (b) (4) removal and prevention of (b) (4) formation. As a result, your firm has not established that the 2008 series including the current configuration 2008 T Blue Star Hemodialysis Machine's internal hydraulic circuit disinfection process is capable of meeting its intended performance under actual or simulated use conditions.

OBSERVATION 4

Information gathered in the feedback process does not adequately serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

Specifically,
Your firm's Feedback Procedure, S100405-01, Rev D, Effective 03/10/2026 requires the monitoring of production and post-production information in accordance with, Production/Post Production Risk

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Management and Risk Review procedure, S100429-03, Rev N, Effective 02/26/2026, and based on the outcome of the review, the risk document may be updated and an improvement process implemented to maintain the product requirement. S100429-03 procedure requires you to identify if there is evidence of a new hazard, hazardous situation, harm or cause that was not identified in the relevant hazard analysis and your Safety Risk Management Procedure, S100429-01, Rev P identifies risk/hazard analysis require to assess reasonable foreseeable misuse; however, you failed to follow your procedures as per the following:

A. Despite identifying the foreseeable misuse scenario of operating the 2008T Series Hemodialysis Machine in patients below the 20 kg minimum weight specification from at least two separate hospital institutions, your firm failed to conduct a risk hazard analysis or update Risk/Hazard Analysis 508152, as required by S100429-03 Section 4.1.2. Complaint # C-1298530, dated 11/18/2024 reported for excess fluid removal, involved a 12-month-old male patient weighing 8 to 9 kg who experienced multiple episodes of hypotension over 6 to 9 months during HD therapy. The complaint documents that the user was unaware of the machine's minimum weight limit, and the facility used the machine exclusively for neonatal and pediatric patients. Complaint # C-1397358, dated 07/21/2025, reported that a different facility was also using the 2008T off-label in patients weighing less than 20 kg across multiple machines, with fluid removal consistently approximately 250 mL more than the machine indicated, ranging from 200 mL to 1.2 L of excess removal. Neither complaint resulted in updates to the risk management file.

B. The 2008 Series Hemodialysis Machines calculate and deliver UF based on programmed total volume and treatment time (mL/hr) without weight-normalized safety checks. Your firm has not established adequate safeguards or warnings to prevent excessive ultrafiltration rates relative to patient body weight, despite awareness through clinical feedback from NC Record # 1310972, dated 02/01/2023 that UF rates exceeding 10 mL/kg/hr represent a risk to patient health.

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OBSERVATION 5

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically,
Your firm failed to initiate corrective action when required by its own procedures, failed to ensure corrective action effectiveness as required by Corrective Action Procedure No. S100006-03, Rev. J, Effective 12/18/2025, and Product Complaint Investigations Procedure No. S101448-01, Rev. AC, Effective 04/16/2025. Additionally, the CAPA procedure failed to establish adequate timelines for corrective action initiation.

A. No corrective action was initiated despite the firm identifying widespread contraindicated use of the 2008T in neonatal and pediatric patients below the 20 kg minimum weight specification in at least two clinics. Complaint # C-1298530 dated 11/18/2024 documents a neonate experiencing multiple episodes of hypotension during hemodialysis therapy, representing a new risk that meets the CAPA initiation criteria defined in S101448-01, Appendix C, Questions 3 and 5.

B. 7 of 7 reviewed death-related complaints received for the 2008T Hemodialysis System from 10/20/2024 to 03/20/2026 did not have a CAPA initiated, as required by S101448-01, Product Complaint Investigations, Rev AC, Effective 04/16/2025, Appendix C, Question 5, despite 3 of 7 complaints documenting UF pump out-of-specification findings post-event and 1 complaint identifying an expired DIASAFE filter in use at the time of the patient's death. For example, the CAPA decision for (b) (6), (b) (7)(C) ((b) (6), (b) (7)(C)) was documented as "No CAPA Required" despite a patient death occurring 12 to 16 minutes into treatment, with post-event testing confirming multiple device malfunctions including UF pump out-of-specification, pressure-holding test failure, air separator leak, and alarm failure — findings that, together with a patient death, directly

meet the CAPA initiation criteria defined in S101448-01, Appendix C, Question 5.

C. From 10/20/2024 – 03/20/2026, your firm received the following complaint volumes for the 2008T Hemodialysis Machine, and each associated with potential (b) (4) (serious injury) severity harm, identified by your firm's own hazard risk analysis: 1,738 Calibration related, 2,199 Conductivity related, 533 Preventive Maintenance related and 159 UF Pump related. Specifically, at least 7 out of 159 UF pump complaints involved hypotension and patient injury, where 1 out of 7, C-1413511 dated August 2025, a patient lost consciousness and was transported to emergency due to UF over removal, and 2 out of 7, (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C), and (b) (6), (b) (7)(C) involved death with the complaints received for UF rate problem. Complaint C-1308963, dated 12/16/2024, reported that a Fresenius 2008T Hemodialysis machine failed to remove the prescribed fluid goal during a patient's treatment, with no alarm activated; the customer was advised to update the software. Complaint C-1475695, dated 01/27/2026, reported an out-of-box UF pump failure; upon return, the UF pump was found to have cable damage, which your firm confirmed on 02/17/2026 was the cause of the UF pump failure. Additionally, (b) (6), (b) (7)(C) not included in the list, identified UF out of specification and involved death (b) (6), (b) (7)(C)). No corrective action was initiated to investigate and eliminate the root cause of these recurring nonconformances contrary to S101448-01, Rev. AC, Appendix C, Question 6, which requires CAPA initiation for systemic issues.

D. Corrective and preventive actions taken to correct and prevent recurrence of blood leak complaints are not adequate. CAPA 1141369, opened August 4, 2022, was initiated in response to dialyzer lot 22DU07003 (b) (4) exceeding the complaint threshold for symptom code (b) (4) – Leak, External, with scope later expanded to include internal leaks and across multiple dialyzer production and lines; the CAPA was declared effective and closed on September 17, 2025, based on a (b) (4) complaint rate of (b) (4) for manufacture dates December 2024 through May 2025. During the effectiveness monitoring period, NC 2136374 opened 06/16/2025 documented that lot 25CU01004 exceeded the firm's defined complaint trigger threshold.

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However, CAPA 1141369 still closed the CAPA as effective on 09/17/2025. Following CAPA 1141369 closure, 282 additional blood leak complaints were received within six months. Notably, lot 25KU04012 received 9 blood leak complaints within two days (January 6–7, 2026), exceeding the firm's complaint trigger threshold.

E. Corrective Action Procedure S100006-03, Rev. J, and Supplier Nonconformance and Corrective Action Work Instruction WI100395-03, Rev. B, Effective 01/18/2025, do not define timelines for CAPA or SCAR initiation, requiring only that actions be taken "as soon as possible." This has resulted in the following:

I. SCAR 2378860 was opened in February 2026 for failures of the Level Detector Module intended to monitor the level of fluid in the venous drip chamber incorporated in the 2008T (b) (4) severity / death-related hazard), which referred to 236 related complaints received from March 1, 2025 through February 18, 2026. As of the inspection date, no root cause investigation has been initiated.

II. SNCR 1817465 was opened July 23, 2024 for failure of 127 affected units of blood pressure cuffs (PN (b) (4)) used with the 2008T. SCAR 1929398 was not initiated until November 21, 2024. As of April 2026, the SCAR remains in progress with only root causes identified and no corrective action plan or implementation completed, despite a SCAR completion due date of April 30, 2025 and a scheduled implementation date of July 11, 2025, with no documented justification. From November 21, 2024 through March 20, 2026, your firm received at least 1,252 complaints for blood pressure-related problems involving the 2008 Series machines, including failure to pressurize, failure to deflate, high and low pressure readings, reading errors, and cuff damage. Blood pressure is monitored during dialysis treatment to monitor fluid balance.

F. Your firm initiated Class II Recall RES 96827 on April 27, 2025, to remove affected lots of 5008X

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Bloodlines experiencing leaks causing blood loss, encompassing 9 lots distributed to (b) (4) Following implementation of corrective actions under CAPA 2016752, and while the recall remained open, bloodlines that had undergone the correction continued to experience leaks resulting in reportable blood loss events of the same type of harm addressed by the original recall, but originating from a different defect location. Despite the recurrence of the same patient harm in corrected product during the open recall period, your firm failed to expand the scope of the field corrective action and failed to re-evaluate if the corrective action from CAPA 2016745 was effective and did not assess whether it introduced new non conformances. There was no documented justification for this decision.

OBSERVATION 6

Criteria for the evaluation and selection of suppliers were not adequately established.

Specifically,

A. Your firm's procedure Supplier Monitoring and Escalation, WI100395-05, Rev. A, Section 4.2.1.3(d) fails to define objective measurable criteria for prolonged unacceptable performance, leaving escalation thresholds undefined. As a result, the supplier of the NovaLung System (Class II, initial importer) remains in approved status with a satisfactory performance, despite prolonged nonconformances across the NovaLung System and its disposables (Sensor Box, Console/Board, XLung Kit) resulting in at least 70 complaints from 10/17/2024 to 04/06/2026 including 2 deaths, and a demonstrated failure to achieve lasting corrective action. Despite this history, your firm introduced a new product (NovaLung Ultimate Kit), without documented evidence that the supplier's systemic quality deficiencies had been resolved. NovaLung System is a Class II device indicated for long-term respiratory and cardiopulmonary support.

B. During the supplier assessment, your firm inconsistently categorized identical components. For example, keyboard P/N (b) (4) is identified as Category (b) (4) (high) for one supplier versus

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Category (b) (4) (moderate-low) for a different supplier. Per Supplier Management System S101446-01 Rev Y, Effective 06/23/2025, Section 4.2.1, the supplier risk categorization framework defines (b) (4) categories with decreasing risk levels, where Category (b) (4) is the highest risk and Category (b) (4) is No Impact. Additionally, WI100395-04, Rev. B, Supplier Audits (Effective 03/30/2026), Table 1 further classifies Category (b) (as High Impact and Category (b) (4 as Moderate-Low Impact. This inconsistency means one supplier requires Level (b) (4) Quality Assurance Agreement and mandatory onsite audits every (b) (4) per WI100395-04 Table 1 and Form F101446-08, Rev I, while another supplier requires only Applicable Supplier Questionnaire with no periodic audits.

***DATES OF INSPECTION**

3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri), 3/31/2026(Tue), 4/01/2026(Wed), 4/02/2026(Thu), 4/03/2026(Fri), 4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/13/2026(Mon), 4/17/2026(Fri), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/27/2026(Mon), 4/29/2026(Wed), 4/30/2026(Thu), 5/04/2026(Mon), 5/05/2026(Tue), 5/08/2026(Fri), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/22/2026(Fri), 5/28/2026(Thu), 5/29/2026(Fri), 6/02/2026(Tue), 6/03/2026(Wed)

X Thomas Siebertz
Investigator
Signed By: THOMAS J. SIEBERTZ -S
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Francis S. Kim, Senior Vice President of North America Quality and Quality Operations

FIRM NAME	STREET ADDRESS
Fresenius Medical Care Renal Therapies Group, LLC	920 Winter St Bld 920
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waltham, MA 02451-1521	Manufcaturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sunita Pandey, Investigator Thomas Siebertz, Investigator X Sunita Pandey Investigator Signed By: 2003030873 Date Signed: 06-03-2026 16:24:21	6/3/2026

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."