DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/2/2026-3/27/2026* FEI NUMBER 1000142899

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Rachael A. Nelsen, Vice President of Quality and Regulatory	
FIRM NAME	**STREET ADDRESS**
Nipro Renal Soultions USA, Corporation	509 Fishing Creek Rd
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Lewisberry, PA 17339-9517	Medical Device 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

Product which does not conform to product requirements was not identified and controlled to prevent its unintended use or delivery.

Specifically,

1. On 05/06/2025, your firm released and shipped (b) (4) cases of MedicaLyte Bicarbonate Powder (45X) (Lot (b) (4) expiration date 04/30/2027) with an out of specification endotoxin result of (b) (4) /mL. The endotoxin specification is (b) (4) /mL. Your firm did not notify your customer regarding the nonconforming product.

2. On 03/26/2026 while fulfilling record requests, your firm discovered the following:
   - On 12/18/2025, your firm released and shipped (b) (4) cases of MedicaLyte Bicarbonate Powder (DB+201-25) (Lot (b) (4) expiration date 12/05/2027) with an out of specification endotoxin result of (b) (4) (b) (4) mL. The endotoxin specification is (b) (4) mL.
   - Lot (b) (4) of the Citric Complete Dry Citric Acid Concentrate, quantity (b) (4) cases, has an out of specification endotoxin result of (b) (4) mL. The endotoxin specification is (b) (4) /mL.
     -On 05/29/2025, (b) (4) cases were shipped
     -On 06/02/2025, (b) (4) cases were shipped

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-On 06/17/2025, (b) (4) cases were shipped

OBSERVATION 2

A design and development file was not maintained for each medical device type or medical device family.

Specifically, your firm manufactures the following Class II medical devices used for hemodialysis treatment of patients with renal failure or toxemic conditions:

- Citric Complete (K223431) – Citric Complete Liquid Citric Acid Concentrate
- Dry Complete (K193155) – Nipro Dry Complete Dry Acid Concentrate for Hemodialysis
- Citric Complete (K171750) – Citric Complete Dry Citric Acid (45X)
- MedicaLyte (K012547) – HEMO-LYTE Hemodialysis Grade Sodium Bicarbonate Solution
- MedicaLyte (K131202) – MEDICALYTE® Bicarbonate Powder (36.83X), MEDICALYTE® Bicarbonate Powder (45X), MEDICALYTE® Bicarbonate Powder (35X)
- MedicaPure (K901471) – GC-1000 Through GC-3005 Acid Concentrate

Your procedure, NRSU-SOP-0018 Design Control [Revision 00, Effective Date 05/01/2020], page 2, states the purpose of this procedure is (b) (4) (b) (4) On page 3, it states (b) (4) (b) (4)

(b) (4)

Your quality manual, NRSU-MAN-0001 Quality Manual Management Responsibility [Revision 01, Effective Date 04/21/2025], page 15, section 8 Design Control, describes your design control process, which includes

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maintaining the following records:

-Design and development
-Design input
-Design output
-Design review
-Design Verification and Validation
-Design transfer
-Design Changes
-Design History file

Your firm does not have design records for all hemodialysis products manufactured at your facility. Further, your firm could not demonstrate your firm conducted design risk analysis, verification activities, validation activities nor established acceptance criteria.

OBSERVATION 3

Procedures to control design and development changes were not adequately documented.

Specifically, your NRSU-SOP-0018 "Design Control" [revision 00, effective Date 05/01/2020] procedure does not include a process to conduct design changes. Your Quality Manual references NRSU-SOP-0019 "Change Control" as the procedure that governs design changes. However, NRSU-SOP-0019 "Change Control" [revision 01, effective date 03/20/2025] does not include how to evaluate the impact of design changes on customer needs, design verification and validation activities, design review, or design transfer. Additionally, your firm did not maintain design change records, nor was design risk analysis conducted to assess potential hazards associated with the following design changes:

-In September 2023 your firm transitioned from (b) (4) packaging for your dry MEDICALYTE® Bicarbonate Powder and Complete Dry Acid Concentrate product line. Your firm made changes to the thickness of the primary packaging film from (b) (4) for both dry product lines.
-On 03/24/2025 your firm changed the final acceptance testing for the endotoxin level specification from (b) (4) (b) (4) mL to (b) (4) /mL for the Liquid Citric Acid Concentrate LC 228 (45x).

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-On 03/24/2025 your firm changed the final acceptance testing for the endotoxin level specification from (b) (4) (b) (4) mL to (b) (4) /mL for (b) (4) of your Liquid Acidic Concentrate [varying concentrations and volume] products.
-On 04/23/2025 your firm changed the final acceptance testing for the endotoxin level specification from (b) (4) (b) (4) mL to (b) (4) mL for the Liquid Acidic Concentrate AC 213 (45x).

OBSERVATION 4

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

Specifically, the following CAPAs failed to implement adequate corrective actions to prevent reoccurrence of quality deficiencies:

-On 5/22/2025, your firm initiated CAPA 25005 for failing to follow the procedures established in NRSU-SOP-0037 Monitoring Production Systems. The Quality Packet contains documents from the maintenance, production, and laboratory departments. These documents are reviewed by the Quality Department for completion, and to assure all production systems are being properly maintained and are found within specification. The production department is responsible for routing appropriate maintenance forms and sanitization forms to the Quality Department. The production department is also responsible for notifying the Quality Department of any deviations or discrepancies from completing the preventative maintenance or sanitization programs. However, the review of the September 2025, November 2025, and January 2026 Quality Packets revealed multiple deficiencies, including missing and incomplete forms.

-On 06/04/2025, your firm initiated CAPA 25010 because "Sample Ports outlined in NRSU-SOP-0039 (b) (4) Monitoring of the (b) (4) System were not fully tested every (b) (4) with some not being tested at all some (b) (4) with no comments to identify why testing was not completed." However, the review of January 2026 monitoring records for the (b) (4) system revealed the following deficiencies:

-Multiple sample (b) (4) tests were not conducted for both colony count and endotoxin monitoring
-No comments were documented to explain why testing was not completed

-On 08/04/2025 your firm initiated CAPA 25014 to correct severe facility and equipment maintenance issues,

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including corrosion, and contamination, and poor environmental controls in the (b) (4) room. On 09/11/2025, your firm initiated CAPA 25019 to address your firms lack preventative and calibration oversight of laboratory and production equipment. Yet your firm initiated an additional CAPA, CAPA 25027 on 11/11/2025, for deficiencies in equipment identification, labeling, preventative maintenance execution, and calibration management. Several pieces of equipment were missing required tags or were overdue for maintenance or calibration, and associated documentation such as logs and records was incomplete or inconsistent. CAPA 25014, 25019 and 25027 remain open. Yet deficiencies in the preventative maintenance and calibration for laboratory and production equipment remain ongoing. For example:

-On 02/02/2026, investigation INV 26020 was initiated after discovery that your metal detector had exceeded its (b) (4) calibration due date by (b) (4) and was found to be out of calibration. Your firm conducted a (b) (4) inspection of all affected products remaining in your inventory, (b) (4) cases, by rerunning products through the metal detector. However, your firm did not take action for products already released and distributed to customers. A total of (b) (4) cases of Medicalyte Bicarbonate Powder and Citric Complete Dry Citric Acid Concentrate were affected.

-During review of the January (b) (4) Checklist for the (b) (4) Area, multiple (b) (4) were missing entries without documented explanations for why maintenance was not performed. Furthermore, a facility tour conducted on February 13, 2026, revealed product residue accumulated on and suspended from the bottle filling machine nozzles used for liquid products.

-For January 2026, your firm's (b) (4) and (b) (4) equipment preventative maintenance records are incomplete.

OBSERVATION 5
Maintenance records have not been adequately maintained.

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Specifically,

A. deficiencies were observed in the following equipment maintenance records:

1. Your work instruction NRSU-WI-006, "Endotoxin Analysis using (b) (4) " (Revision 03, effective 12/03/2025), states on page 4: (b) (4) (b) (4) Your (b) (4) (serial number (b) (4) is critical in determining quantitative endotoxin levels in:

- (b) (4) water system monitoring
- Final acceptance testing for Dry Acidified concentrate, Citric Acid concentrate, and Bicarbonate concentrate
- Final acceptance testing for Liquid Acidified concentrate, Citric Acid concentrate and Bicarbonate concentrate solutions

Despite the criticality of this equipment and your firm's written procedure requiring (b) (4) calibration, your firm has (b) (4) calibrated the (b) (4) Additionally, your firm does not have a calibration schedule in place for the (b) (4)

Page 26 of the (b) (4) Operator Manual states: (b) (4) (b) (4) However, your firm has not changed the (b) (4) and does not have a preventive maintenance schedule in place to ensure maintenance is performed according to the vendor's recommendations.

2. Your firm has NRSU-WI-0012 "Calibrations" [Revision 00, Effective date 04/10/2020] in place that establishes a calibration program for equipment used in the manufacturing and testing of components and finished products. Your firm also has NRSU-FRM-0299 "Calibration Intervals and Standards" [Revision 00, effective date 04/24/2020] which describes calibration frequency, responsibility and calibration standards. However, your firm could not identify which equipment requires calibration.

3. For your bottle filling equipment used for the Liquid Citric Acid Concentrate, Liquid Acid and Liquid Bicarbonate Hemodialysis solutions, your firm did not perform (b) (4) maintenance for January, February, and

March 2025. Additionally, during the facility tour on February 13, 2026, product residue was observed both accumulated on and suspended from the nozzles of the bottle filling machine used for liquid products.

4. For the period of September 2024 to February 2026, your firm did not provide (b) (4) or (b) (4) equipment preventative maintenance records.

5.For the period of January 2025 to February 2026, your firm did not provide (b) (4) equipment preventative maintenance records, with the exception of March 2025.

6. For the period of September 2024 to February 2026, your firms (b) (4) and (b) (4) equipment preventative maintenance records were incomplete

7. NRSU-SOP-0037 "Monitoring Production Systems" [Revision 00, original date 04/13/2020] states the purpose of this procedure is to define the method for monitoring production systems and applies to the specified maintenance activities, (b) (4) Transfer Hoses, the Facility (b) (4) System, Laboratory (b) (4) system, (b) (4) system, Laboratory Equipment, and Sanitization Processes. Page 2, states "…Quality Packet that contains a multitude of documents from maintenance, production, and laboratory. These documents are reviewed by the Quality Department for completion, and to assure all production systems are being properly maintained and are found within specification."

However multiple deficiencies were found in the review of the January 2026, November 2025 and September 2025 (b) (4) Quality Packets, for example:

- Various missing and/or incomplete equipment (b) (4) and (b) (4) maintenance
- Missing and/or incomplete (b) (4) system maintenance and microbial testing.

B. Infrastructure requirements needed to achieve conformity to product requirements have not been adequately maintained.

Specifically,

1. Your (b) (4) systems are used to manufacture Liquid Citric Acid Concentrate, Liquid Acid Concentrate, and Liquid Bicarbonate Hemodialysis solutions, as well as to sanitize the (b) (4) (b) (4) used to store and ship the Liquid Citric Acid Concentrate and Liquid Acid Concentrate. The following

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maintenance deficiencies were identified:

(b) (4) Operational Maintenance Records:
Missing or Incomplete records for January 2025 to January 2026

(b) (4) Operational Maintenance Records:
Missing Records for January and February 2025

(b) (4) Operational Maintenance Records:
Missing Records for January and February 2025

Endotoxin and Microbial Testing Records:
Missing or incomplete Records from September 2024 through February 2026

2. NRSU-WI-0040 [Revision 00, effective 03/30/2020] "Operation of the Water System" page 2, section IV states (b) (4) (b) (4) When asked who is responsible for ensuring the (b) (4) system operates during non-manufacturing days (b) (4) your general manager stated that a maintenance employee is assigned this responsibility. However, when requested, your firm failed to provide documentation demonstrating that the (b) (4) system operates for a minimum of (b) (4) minutes (b) (4) hours, as required.

3. NRSU-WI-0040 [Revision 00, effective 03/30/2020] "Operation of the Water System" page 6 states (b) (4) (b) (4) (b) (4) However, your firm failed to provide records demonstrating that your (b) (4) were replaced from January 2025-February 2026.

4. NRSU-WI-0010 "Sanitization of Tanks and Product Supply Lines" [Revision 01, effective 07/28/2021] describes the sanitization process for (b) (4) (b) (4) used for (b) (4) transfer. In the review of records dating from October 2024 to January 2026 your firm did not adhere to the (b) (4) sanitization schedule included in NRSU-WI-0010. Further, your firm failed to provide (b) (4) sanitation records for October 2025 and November 2025.

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5. As required by your procedure, NRSU-WI-0040 [Revision 00, effective 03/30/2020] "Operation of the Water System", for the period of January 2025-November 2025 your firm could not provide:

-NRSU-FRM-0051 "(b) (4) System (b) (4) Operational Log" which is used to document (b) (4) (b) (4)

-NRSU-FRM-0052 "(b) (4) System (b) (4) Membrane Operational Log" which is used to document (b) (4)

-NRSU-FRM-0053 "(b) (4) "

6. Your procedure NRSU-WI-0040 "Operation of the Water System" (Revision 00, effective 03/30/2020) does not include remedial actions to be taken in response to pipe leaks. Additionally, no procedure is in place to evaluate the effect of leaking pipes on product safety and efficacy.

a) Your firm does not maintain records for pipe replacement or pipe repairs for your (b) (4) (b) (4) systems. For example:

-A pipe burst occurred on December 15, 2025, involving the pipes carrying (b) (4) water. Your firm could not provide documentation of the repairs performed following this incident.

-The (b) (4) system used to sanitize the (b) (4) for your Liquid Acid and Liquid Citric Acid Hemodialysis solution consists of both old and new piping. However, your firm could not provide:

-Records documenting when new pipes were installed

-Validation or requalification studies demonstrating that the system continues to function as intended following new pipe installation

b) During a tour of your (b) (4) systems on February 13, 2026, the following were observed:

(b) (4) System for Hemodialysis Liquid Products:

-One pipe leak was observed in the (b) (4) (b) (4) treatment).

(b) (4) System for Sanitizing (b) (4) (Liquid Acid Hemodialysis Solutions):

-One pipe leak was observed in the (b) (4)

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(b) (4) treatment).

-Two pipe leaks were observed in the (b) (4) (b) (4) treatment).

For the pipe leaks, your firm did not document:
- -Root cause analysis
- -Repair plans or corrective actions
- -Records of completed or scheduled repairs
- -Impact assessment on manufacturing operations

OBSERVATION 6

Records of the results and conclusion of validation of processes and necessary actions from the validation were not maintained.

Specifically, since 12/18/2023, the (b) (4) [serial number (b) (4) has been in use to monitor endotoxin levels in the (b) (4) system and final release endotoxin testing for (b) (4) your products.

However, your firm did not conduct validation for the (b) (4) to detect endotoxin levels in your (b) (4) system and endotoxin testing for the following product lines:
- -Liquid Acidic Concentrate for Hemodialysis endotoxin level
- -Liquid Citric Acid Concentrate for Hemodialysis endotoxin level
- -Liquid Sodium Bicarbonate Hemodialysis Solution endotoxin level

Though your firm validated endotoxin testing level (b) (4) mL for various concentrations of your Dry Citric Acid, in addition to the Dry Bicarbonate Powder concentrate DB+201-25. Your firm did not include validation for the endotoxin testing level (b) (4) /mL for various concentrations of your Dry Citric Acid concentrates and Dry Bicarbonate products.

Further, your firm did not validate retesting of out of specification endotoxin results for your (b) (4) system

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testing and final release testing for your hemodialysis products.

OBSERVATION 7

Evidence of conformity to the acceptance criteria for product monitoring and measurement was not adequately maintained.

Specifically, on 07/14/2025, investigation INV 25051 was initiated after final review revealed that endotoxin results for AC+226 (lot (b) (4) and LC+203 (lot (b) (4) were out of specification. Both lots were documented as passing ((b) (4)mL) on the Laboratory Report form; however, lot (b) (4) had an actual endotoxin result of (b) (4) mL and lot (b) (4) had an actual endotoxin result of (b) (4) mL. The laboratory form listed the endotoxin specification as (b) (4)mL, which conflicted with the reported passing criteria.

In reviewing your laboratory forms for the Acidified Hemodialysis concentrate the following were observed:

-The laboratory form for (b) (4) Acidified Hemodialysis concentrate (various concentrations and volume) lists the endotoxin level specification as (b) (4)mL.
-The laboratory form for (b) (4) Acidified Hemodialysis concentrate (various concentrations and volume) lists the endotoxin level specification as (b) (4)mL.
-Your NRSU-DMR-0020 device master record for the Acidified Hemodialysis concentrate [AC 202] lists the endotoxin level as (b) (4)mL.

Your firm's endotoxin specification for Liquid Citric Acid Concentrate LC228 (45x) is (b) (4)mL for , while all other products within this product line have an endotoxin specification of (b) (4)mL

Your firm's endotoxin specification for the Liquid Acidic Concentrate AC 213 (45x) is (b) (4)mL, while all other products within this product line have an endotoxin specification of (b) (4)mL.

OBSERVATION 8

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Records of the nature of nonconforming product and any subsequent action taken, including the evaluation, and any investigation and the rationale for decisions, were not maintained.

Specifically, your procedure NRSU-SOP-0060 "Investigations" describes the process to initiate an investigation for out of specification lab results. For January 2025-Feburary 2026 your firm did not initiate an investigation for 13 product related endotoxin failures, in addition to 12 (b) (4) monitoring endotoxin failures.

OBSERVATION 9

A record for each medical device or batch of medical devices that provides specified traceability and identifies the amount manufactured and amount approved for distribution has not been established and maintained.

Specifically, in reviewing batch records for your hemodialysis products, the following deficiencies were observed:

-Scraps generated during production are not documented in the batch records
-Endotoxin level failures and subsequent retesting are not included in the batch records
-Quantity of products disposed are not documented
-Quantity of product distributed is inaccurate
-Rework documentation
-Repackaging documentation

OBSERVATION 10

Complaint handling records were not adequately maintained.

Specifically, the following deficiencies were observed in the review of your complaint records:

-Your procedure NRSU-SOP-0068 "Complaint Handling" [Revision 01 effective date 12/02/2024], page two, section 7.1.3 states (b) (4) . However, eight complaints

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CITY, STATE, ZIP CODE, COUNTRY Lewisberry, PA 17339-9517	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

remained open beyond (b) (4) days.
-Five complaints lacked determination of whether an investigation or CAPA is warranted.
-For Complaint 26010 (01/08/2026) – Nipro's North American headquarters in Miami, FL initiated Complaint 2025-0699 on 10/22/2025 regarding a customer report of high (b) (4) eadings in (b) (4) cases of LC+225. Your facility did not initiate the corresponding complaint (26010) until 01/08/2026, representing a (b) (4) delay.
-Your firm does not consistently document the brand or model number of dialysis machines involved in (b) (4) complaints as demonstrated in complaints: 24006, 25153, 25137, 26002, 26010 and 26011.

OBSERVATION 11

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically, your firm has not established a systematic, risk-based approach to identifying, evaluating, and controlling risks associated with your quality management system processes, product design, and manufacturing operations. Your firm does not have the following procedures:

-Risk management procedure for the overall Quality Management System (QMS)
-Design risk analysis procedure
-Process risk analysis procedure

OBSERVATION 12

Medical device files have not been adequately established and maintained.

Specifically, your firm has not updated the medical device files to reflect the following changes:

-Endotoxin level specification changes for your Liquid Citric Acid concentrate and Liquid Acidic Concentrate products.
-In September 2023 your firm transitioned from (b) (4) packaging for your dry concentrate products. Your firm made changes to the (b) (4) of the primary packaging film from (b) (4) for

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/2/2026-3/27/2026* FEI NUMBER 1000142899

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
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both dry products.

OBSERVATION 13

Supplier performance in meeting requirements for the purchased product was not monitored.

Specifically, your procedure NRSU-SOP-0022 "Supplier Management" describes your firms process to classify and evaluate your suppliers. However, your firm has not conducted supplier evaluations for the suppliers and services used to manufacture your Liquid Bicarbonate solution, BC+201 and Dry Citric Acid, DCA+ 225 products.

OBSERVATION 14

Requirements for the work environment, and the procedures to monitor and control the work environment, were not documented where conditions for the work environment can have an adverse effect on product quality.

Specifically, the finished labeling for your firm's hemodialysis products includes humidity and storage conditions. Your firm's NRSU-MAN-001 "Quality Manual" [Revision 01, effective date 04/21/2025] includes section 12.3 Environmental control, page 18 which states "NRSU-SOP-0089, Environmental Monitoring, Environmental controls are maintained commensurate with the function of each area." Yet when requested, your firm stated your firm does not have NRSU-SOP-0089, Environmental Monitoring procedure.

OBSERVATION 15

Internal audits have not been adequately conducted at planned intervals to determine whether the QMS is effectively implemented and maintained.

Specifically, your procedure NRSU-SOP-0001, "Internal Audit" (Revision 01, effective 09/04/2024), states on page one: "...this procedure provides guidelines by which NRSU shall evaluate itself for compliance with applicable regulatory standards and to its own written procedures." According to this procedure, your firm is required to conduct internal audits at least (b) (4)

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However, your firm failed to conduct internal audits from 2020 through 2023. While your firm conducted a partial internal audit on 10/30/2024, this single audit does not fulfill the (b) (4) requirement described in your internal audit procedure.

***DATES OF INSPECTION**

2/02/2026(Mon), 2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/11/2026(Wed), 2/12/2026(Thu), 2/13/2026(Fri), 2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri), 3/04/2026(Wed), 3/05/2026(Thu), 3/06/2026(Fri), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: Not annotated

Observation 9: Not annotated

Observation 10: Not annotated

Observation 11: Not annotated

Observation 12: Not annotated

Observation 13: Not annotated

Observation 14: Not annotated

Observation 15: Not annotated

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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."