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SUMMARY

This was an unannounced routine surveillance inspection of drug repackager and relabeler Eminent Services Corporation, conducted under eNpect Operation ID#315142 and FACTS ID#12429680. This inspection was conducted in accordance with the FDA Compliance Programs 7356.002B, Drug Repackagers and Relabelers, and 7356.002A, DPI/Small Volume Parenterals (Sterile Drug Process Inspections). Inspectional coverage was for the profile code SVS – sterile-filled small volume parenteral drugs and SVL– small volume parenteral (Lyophilized).

The previous FDA inspection of the firm was conducted from 02/03/2020 to 02/06/2020 and was classified as "No Action Indicated" (NAI).

At the conclusion of the inspection on 04/28/2025, a four (4)-item Form FDA 483, Inspectional Observations, was issued to Mr. Sombabu Mullapudi, CEO, EMINENT Services Corporation, for the following observations. 1) Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. 2) Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance. 3) The responsibilities and procedures

[redacted] applicable to the quality control unit are not fully followed. 4) Written procedures are not drafted, reviewed and approved by the appropriate organizational units.

Mr. Sombabu Mullapudi, CEO, EMINENT Services Corporation, stated that a written response would be submitted to the FDA within 15 business days. The firm's drug registration is current. No samples were collected, and no refusals were encountered during the inspection.

ADMINISTRATIVE DATA

Written by PSJ)

Inspected firm:	EMINENT Services Corporation
Location:	7495 New Technology Way Frederick, MD 21703-9401
Phone:	240-629-1972
FAX:	240-629-3298
Mailing address:	7495 New Technology Way, Frederick, MD 21703-9401
Email address:	PThadikonda@emiserv.com
Inspected firm:	EMINENT Services Corporation
Location:	7495 New Technology Way Frederick, MD 21703-9401
Website:	www.emiserv.com
Dates of inspection:	4/24/2025-4/25/2025, 4/28/2025
Days in the facility:	3
Participants:	Pushpa S Jayasekara, Investigator Michael O Idowu, Investigator Azeezat M Lawal, Investigator

On 04/24/2025, I lead Investigator Pushpa S. Jayasekara, and Investigators Michael O. Idowu, and Azeezat M Lawal arrived at the firm, presented our credentials and issued a "Form FDA 482, Notice of Inspection" (**Attachment 1**) to Mr. Sombabu Mullapudi, CEO, EMINENT Services Corporation, who identified himself as the most responsible person on site. Mr. Anbu Devasahayam, President, and Mr. Arun Kantareddy, Vice President of Operations, were also present at the opening meeting. During the opening meeting, we explained to the firm management that the purpose of our visit was to evaluate the firm's CGMP operations.

On 04/28/2025, a four-item Form FDA 483, Inspectional Observations, to Mr. Sombabu Mullapudi (**Attachment 2**). Mr. Mullapudi agreed to respond to the FDA-483, in writing, in 15 business days.

This Establishment Inspection Report (EIR) was collaboratively written by Lead Investigator Pushpa S. Jayasekara, Investigator Michael O. Idowu and Investigator Azeezat M Lawal. The terms, "We", "Our", and "us" refers to Investigators Pushpa S. Jayasekara, Michael O. Idowu and Azeezat M Lawal. Initials 'PSJ' represents Lead Investigator Pushpa S. Jayasekara, initials 'MOI' represents Investigator Michael O. Idowu, and initials 'AML' represents Investigator Azeezat M Lawal. "I" refers to the Investigator that is identified as the author of the applicable section. For the purposes of this report, Eminent Services Corporation will henceforth be also referred to as the "firm" or "Eminent" throughout this report.

Post-inspectional correspondence should be addressed to:
Mr. Sombabu Mullapudi

[redacted]
Eminent Services Corporation
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HISTORY
(Written by MOI)
As stated in the previous inspection report, the firm has ceased the repackaging and relabeling of [redacted] for the U.S. market and has decommissioned related batch records since August 2015. Mr. Anbu Devasahayam stated that the firm has one client they produce commercial products for, [redacted]
The firm has not made any renovations or changes to their facility since the last investigation. During the opening meeting the firm's management stated that the firm is cable of conducting repackaging/ relabeling processes for commercial products in the US market. In November 2023, Mr. Sombabu Mullapudi assumed the role of CEO, and the firm was acquired by CIAN Diagnostics, but remains its own entity. The firm was established in 1997 as a small business corporation (S-corp), incorporated in Maryland, with the purpose of providing investigational drug management services to sponsors. The firm's business and manufacturing hours are from 8:00am to 5:00pm, Monday to Friday. The firm currently has approximately 30 full time employees with a current re-registration status for 2025.

INTERSTATE (I.S.) COMMERCE and JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
(Written by AML)
100% of the firm's packaging materials are received from outside of the State of Maryland. [redacted] The repackaged and relabeled products were shipped to the non-U.S. market per customer agreement. The management provided a copy of the Bills of Lading (BOL), packing slips, and associated certificates of analysis (CoA) for the packaging materials, unlabeled product and labeled product for [redacted] and Batch record [redacted]

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
(Written by PSJ)
The following individuals were interviewed during the inspection and/or provided copies of requested documents to aid in the inspection. The firm's general organizational chart is provided in **Exhibit PSJ 16**.

Mr. Sombabu Mullapudi, CEO: Mr. Mullapudi has been with the company in the current position since November 2023. His responsibilities include managing the firm's overall operations, general administration of the facility, and business development. Mr. Mullapudi identified himself as the most responsible person on site. He was present during the opening meeting, facility walkthroughs, daily wrap-up meetings, and the closeout meeting.

[redacted]

Mr. Anbu Devasahayam, President: Mr. Devasahayam has been with the firm since September 2003, and was promoted from Vice President to President in January 2019. His responsibilities include managing the firm's overall operations, validation protocols and qualification, general administration of the facility, and business development. He reports directly to Mr. Mullapudi. Mr. Devasahayam was present during the opening meeting, facility walkthroughs, daily wrap-up meetings, documentation review, and the closeout meeting.

Mr. Arun Kantareddy, Vice President, Operations. Mr. Kantareddy has been with the firm since September 2001. His responsibilities include overseeing the operations of the packaging and labeling (P&L), and information technology (IT) departments. He reports to Mr. Devasahayam. Mr. Kantareddy was present throughout the inspection to include the closeout meeting.

Ms. Vijaya Rangavajhula, Vice President, QA/QC. Ms. Rangavajhula has been with the firm since October 2016. Her responsibilities include leading the quality unit, revising standard operating procedures (SOPs), manageing deviations, internal audits, complaints, training, and making changes to batch records based on sponsor provided and internal justification. She reports to Mr. Devasahayam. Ms. Rangavajhula was present throughout the inspection to include the daily wrap-up, closeout meetings, facility walkthroughs, and documentation review.

Mr. Hemanth Sanagapati, Director, QA/QC. Mr. Sanagapati has been with the firm since 2003. He is responsible for overseeing the Quality Assurance (QA)/Quality Control (QC) department and provides final disposition on all finished products, including batch record review. He reports to Ms. Rangavajhula. Mr. Sanagapati was present throughout the inspection to include the daily wrap-up, closeout meetings, facility walkthroughs, and documentation review.

Other personnel who participated and provided information during the inspection include:
Mr. Raghuveera Yaramolu, Director, Packaging & Labeling
Mr. Johnny Perike, Manager, Warehouse
Mr. Raghavendra Motamarri, QA/QC Research Associate
Mr. Manoj Adusumilli, VP IT / Global Operations
Mr. Rajashekar Pingali, Director Manufacturing

FIRM'S TRAINING PROGRAM

(Written by MOI)

The firm's Employee Training: SOP, 5050.08, effective date 01/15/2025 was reviewed. The SOP outlines that new employees participate in orientation, internal and external hands-on training, and SOP instruction. Training is conducted in alignment with the duties outlined in each employee's job description and is delivered through structured presentations, written materials, and SOP's. Employees undergo multi-disciplinary training by rotating through different departments to become proficient in additional SOPs. GMP training is an essential component of initial onboarding and is provided via instructional videos annually through presentations focused on relevant and current topics. I reviewed 4 employee records. no discrepancies were found.

MANUFACTURING/DESIGN OPERATIONS

(Written by PSJ)

[redacted]
The current inspection provided CGMP coverage to the firm's contract repackaging/relabeling process for three commercially approved prescription sterile finished drug products (biologic products) [redacted] for the non-U.S. market customer, [redacted]
According to the firm last repackaging and relabeling activity was completed on 03/15/2024 for product [redacted] The firm was informed by their client [redacted] to destroy any remaining inventory. Please see **Exhibit PSJ 13** for list of repackaging/ relabeling products since 2020.

Over the course of the inspection, walkthroughs conducted on day 1, 2, and 3 of the inspection encompassed key areas including:

- Warehouse, quarantine and release material storage refrigerators, and rejects area.
- Packaging and labeling room (100% manual labeling and packaging process)
- Label storage room and printing room.

The inspection consisted of visual inspection of the firm's facilities and equipment, observation of packaging activities, review of records, and interviews with firm employees.

QUALITY SYSTEM
(All the subsections were written by AML)
Quality Oversight of production Activities:
Per SOP 2000, Authority and Responsibility of Quality Assurance and Quality Control, Effective Date: 04/25/2025. Eminent' s quality system is overseen by the quality assurance and quality control unit (QA/QC) staff. According to the quality agreement between the firm and the client [redacted], final product release is completed by the client [redacted]

Deviations/ change controls/CAPAs
The firm's SOPs that reference, deviations, CAPAs, and change controls are as follows:

SOP ID	Title	Effective date
2012.09	Deviations/Incident Reporting Processing	12/04/2017
2013.06	Corrective and preventative Action	11/27/2024
2029.06	Change control procedure	03/24/2025

The firm utilizes Investigational Drug Management System (IDMS) system for reporting and tracking deviations, change controls and CAPAs. I reviewed SOPs and list of deviations and CAPAs since the last inspection [redacted] with Ms. Vijaya Rangavajhula, Vice President of QA/QC. During the review, it was observed that the firm did not include sufficient evidence detailing the processing or handling of investigations, such as root cause analysis or CAPA (Corrective and preventative actions), effectiveness checks. Please see **FDA 483 observation 4** for details.

Annual Product Review

[redacted]

I reviewed the following Annual product review (APRs) with no discrepancies:

Drug product	APR Review period
[redacted]	April 2021-March 2022
	Jan 2021-Dec 2021
	Jan 2022-Dec 2022
	April 2022- March 2023
	July 2021-June 2022
	Jan 2023-Dec 2023
	April 2023-March 2024
	July 2022- June2023
	Jan 2024- Dec 2024
	July 2023- June 2024

Quality agreements and list of major customers

[redacted]s listed as the firms only customer for the product relabeling and repackaging. I reviewed the quality agreement between the firm and the Takada pharmaceuticals without any discrepancies.

Product recall and Recall Procedure

For product recalls, please see **Recall Procedure.**

PRODUCTION SYSTEM

(Written by MOI)

Overview of production process.

Master batch records approved by the firm's client [redacted]are used to execute client purchase orders. The client provides the firm labels and components for each of their drug products and each drug product has a specific master batch record depending on the final international destination of drug product. Ms. Vijaya Rangavajhula, Vice President, QA/QC, explained that once the firm receives a purchase order, the IDMS system generates a unique Eminent batch record number. The Eminent batch record number and its corresponding specific master batch record are sent to the client for approval. Once approved by the client, the Eminent batch record number is signed off by QA and approved for production at the firm. Based on the work order, the firm prints lot number (generated by IDMS) and expiry (provided by the client) on the product label and embosses the respective lot number and expiry on the product carton, then QA releases these components for the production. The packaging and labeling of the final drug product is conducted using a manual process with operators and QA staff in the designated room. Once this process is completed the product is transferred to internal release storage. QA reviews the Eminent batch record, then it is sent to the client for review and approval. Once approved by the client, it is finally approved by QA and set for release.

Batch record review

I reviewed the [redacted] Batch Records [redacted] produced from 2021 to 2024 in comparison to the [redacted] Master Batch Record and observed no deficiencies.

[redacted]

Batch delabeling and relabeling

SOP,6304.06, effective date: 12/23/2010, demonstrates the procedure for the de-labeling and subsequent relabeling of final products. The firm explained that this procedure is done at the request of the client. The production manager and QA/QC manager will verify that the appropriate product is to be de-labeled based on the requested Batch Record. After de-labeling is complete the lot is received into the firm's IDMS system as an internal transfer and is considered as a new product to be put under quarantine status and receives a new lot number. A de-labeled batch record [redacted] was reviewed with not deficiencies noted.

FACILITIES AND EQUIPTMENT SYSTEM

(All the subjections were written by PSJ)

The firm utilizes a 57,000 sq. ft building housing 31000 sq. ft warehouse and 26,000 of two-floor a administrative office space. Please refer to Site Masterfile **Exhibit PSJ 14** for site map.

Labeling, delabeling and relabeling process

The firm uses 100% manual process for drug product labeling, delabeling and relabeling.

IQ/OQ/PQ and temperature re-mapping of walk-in-refrigerators

The firm has five walk-in-refrigerators [redacted] used in product quarantine and release stages of final drug products including sterile finished drug products (biologic products). I reviewed the qualification (temperature mapping) and temperature re-mapping of refrigerator EE-0386 with Mr. Anbu Devasahayam, President. During this review, I observed temperature probe calibration discrepancies during the equipment qualification and temperature re-mapping process. Please see **FDA 483 observation 2** for details.

Temperature monitoring trends of walk-in-refrigerators

I reviewed temperature trend data for walk-in-refrigerators [redacted] from April 2024- April 2025 and April 2023- March- 2024. The firm uses the [redacted] data acquisition system to monitor temperature of the walk-in-refrigerators. The [redacted] data acquisition system is also equipped with alarm dialer options (calling to staff phone numbers) during excursions. No significant deficiencies were observed.

Warehouse temperature mapping

The firm's warehouse temperature mapping procedure is governed by the SOP 4022.01, titled "Eminent warehouse mapping procedure", effective date: 05/08/2007. I reviewed both the SOP, and temperature mapping protocol and report with Mr. Anbu Devasahayam, President. They have used 14 calibrated, single use, TempTale (manufacture: Sensitech) probes with [redacted] acquisition system for 72 hours, 15 min data acquisition, and covering winter and summer during the mapping process. No significant deficiencies were observed.

Line clearance / Room Cleaning

The firm's cleaning process is governed by the SOP 2020.04, titled "Cleaning, verification and usage of manufacturing rooms and equipment", effective date: 04/25/2025. I reviewed the SOP and room cleaning records (before production run and after production run) with Mr. Hemanth Sanagapati, Director, QA/QC. Mr. Sanagapati stated that package room cleaning certification is a part of the product batch

[redacted]
record. No discrepancies were observed during this review.

Stability
For the commercial product, the firm has not conducted any stability studies. The firm's management stated that the client is responsible for conducting product stability studies and providing the product expiry date.

Pest control
(Written by MOI)
General Maintenance: SOP 4005.13, effective date: 11/13/2023, subsection E, part 4 outlines the firm's Pest Control program. During the walkthrough of the loading dock on 4/24/2025, the firm explained that their pest and rodent control program is contracted with Ehrlich. The outside service provider is contracted monthly to monitor for pest on the inside and outside of the facility, with the use of EPA approved pesticides, glue stick pads, rodent traps, and UV Bug Zappers. A review of the firm's pest control SOP and monthly service contract receipts from January 2023 to present, demonstrate no deficiencies.

MATERIAL SYSTEM
(All the subsections were written by PSJ)
Warehouse
The firm's warehouse inventory system is governed by the SOP 6001.11, titled "Incoming shipment receipt procedure", effective date: 08/12/2024 (**Exhibit PSJ 6**) and SOP 6004.10, titled "Shipping/ transfer procedures", effective date: 08/12/2024 (**Exhibit PSJ 8**). Upon receiving or internal transferring and verification, materials are logged into the IDMS (Investigational drug management system) with scanned copies of bill of lading, COA, and order request. The system then generates an internal serial number (Lot# or tracking number based on the client) and labels to attached on the incoming materials and placed in the quarantine location. After the production (labeling and packaging), the product lot number based on the client (parent), has given a new lot number attached to the firm (EMINENT Services Corporation) (child) and IDMS tracks all the parent-child product cycle. Then moved the labeled product to a release storage area (internal release), prior to final release by the client.

We conducted an inspectional walkthrough of the warehouse, quarantine walk-in-refrigerator (Equipment ID [redacted]), release walk-in-refrigerator (Equipment ID [redacted], and secure rejected material area with Mr. Johnny Perike, Warehouse Manager and the firm's management. Mr. Perike showed us how the barcode labelling is used to track the location of materials in the IDMS system. We randomly selected products and materials in quarantine and release walk-in-refrigerators and rejected material storage in the warehouse to see how the firm uses the IDMS system to track the material. Please see **FDA 483 Observations 3a and 3b** for issues related to product labeling and material tracking process in the warehouse.

Qualification/validation and security of computerized processes
The firm uses in-house developed computerized software system, IDMS (version 2.0) for CGMP activities such as warehouse, production, maintenance, and quality assurance. I reviewed the validation summary of IDMS validation system with Mr. Arun Kantareddy, Vice President, Operations and Mr. Anbu Devasahayam, President (**Exhibit PSJ 3**). During the review, I observed that this software doesn't

[redacted] have audit trail capability to monitor and review CGMP activities. Please see **FDA 483 observation 1** for details.

PACKAGING AND LABELING SYSTEM
(All the subsections were written by PSJ)
The firm's management stated that the firm receives un-labeled products, labels (without printed lot# and expiry date), cartons, tamper-evident seal and package inserts from their client and performs secondary packaging and labeling, and ships labeled drug product. According to the client [redacted] agreement (**Exhibit PSJ 15**), the client is responsible for releasing all packaging components, and unlabeled product and final labeled drug product release. [redacted] products packaging and labeling process is governed by the SOP 0011-08.03, titled [redacted] packaging and labeling procedure", effective date: 02/18/2022. Based on the work order from their client, the firm prints lot number and expiry on the product label and embosses the respective lot number and expiry on the product carton. After QA approval, these components were released to the production for final product labeling and packaging. Firm's lot number is generated through IDMS and the expiry date is provided by the client.

We conducted a secure label storeroom,label design and printing room walkthrough on 04/28/2025 with firm's management. We also observed label printing equipment and label design process. No discrepancies were observed. Mr. Hemanth Sanagapati, Director, QA/QC, explained the label control and reconciliation process. He further stated that label release and reconciliation process is captured in the batch records. We review the batch records (Lot# [redacted] with Mr. Sanagapati and no objectionable conditions were observed.

MANUFACTURING CODES
(Written by PSJ)
No change from the previous inspection. For each new product lot, IDMS generates a four-digit year, a capital letter indicating the type of operation based on the code below and four or five-digit unique sequential event.
B = Packaging and labeling batch record
C = Complaint
D = Deviation
R = Received (five-digit)
S = Shipped (five-digit)

For example,
2023C0014 represents the fourteenth customer complaint received in 2023.
2024B0053 represents the 53rd packaging and labeling batch record created in 2024.

COMPLAINTS
(Written by AML)
The firm's complaint procedures are detailed in SOP 2011, titled "Customer Complaint Processing Procedure", Effective date 09/29/2023, and states, following the receipt of a complaint, it is logged into the IDMS and an Eminent Customer complaint report form #011C is initiated. Next, a sequential complaint number is assigned via a 9-character identifier. A manager is responsible for handling the complaint investigation and CAPA. Investigations are dependent on the type of complaint, review of the

[redacted]
complaint is typically approved within 30 business days unless there is a delay due to client responsibility. Several complaints ([redacted]) were reviewed since 2020, specifically, complaint [redacted] states the root cause as "Operator Error" and goes on to explain an error regarding BR# [redacted] where a Master Batch Record (MBR) was used for execution of the batch incorrectly. [redacted]
record. No discrepancies were observed during above reviews.

RECALL PROCEDURES
The firm's recall procedure is governed by the SOP 6013.08, titled "Standard Operating Procedure", effective date: 09/06/2019. The firm's management stated that the firm conducts recall based on the client's approval, and the firm has not had any product recalls since its last inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE
Observations listed on form FDA 483
(Written by PSJ)

OBSERVATION 1
Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically,

There is no established procedure for reviewing the audit trails within the in-house developed computerized system (IDMS- Investigational drug management system) used for, but not limited to, quality assurance, production, maintenance, and warehouse activities. System administrators are able to alter existing warehouse inventory data in the IDMS—database—inventory reconciliation without QA oversight, and no audit trail function was available to capture such actions.

Reference: 21 CFR 211.68(b)
Supporting Evidence and Relevance:
The firm uses computerized system (IDMS- Investigational drug management system) for their data handing process including input, alter and update their raw data during but not limited to, quality assurance, production, maintenance, and warehouse activities. The firm management stated that the IDMS software is validated for variety of GMP actives. Please see pages 18 to 22 of 402 of the IDMS Validation report for variety of GMP actives, version 2.0, date: 03, **Exhibit PSJ 3** for details. The firm's management also stated that IDMS software doesn't have audit trail capabilities and is not CFR part 11 compliant. Please see **Exhibit PSJ 2** for the memorandum provided the firm stating no audit trail functionally within the IDMS system. We observed that the Mr. Arun Kantareddy, Vice President, Operations, login as system administrator and was able to change the existing warehouse inventory data (quantities) in the IDMS database inventory reconciliation without QA oversight, and no audit trail

[redacted] function was available to capture such actions (**Exhibit PSJ 1**).

During the meeting, the firm management stated that they printed data from the IDMS system, manually sign and archive the hard copies. They also stated they use printed hard copies to release products.

Discussion with Management:
During the daily wrap-up and closeout meeting, firm's management acknowledged our concern of use of CFR part 11 non-compliant computerized system (IDMS) for CGMP activities. Mr. Sam Mullapudi , CEO, stated that the firm would respond to this observation in writing to the agency within 15 business days.

OBSERVATION 2
Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.
Specifically,

Your firm has never calibrated the 16 thermocouple temperature probes (manufacture: Omega) used during the temperature mapping of five refrigerators (2 °C - 8 °C) (Part No: [redacted]. Also, your firm doesn't have established a periodic re-calibration program for above equipment. These refrigerators have been designated to store commercial biological products.

Reference: 21 CFR 211.68(a)
During the IQ/OQ/PQ of five walk-in-refrigerators (2 °C - 8 °C) (Part No [redacted]) in 2010, the firm used 16 thermocouple temperature probes (manufacture: Omega) to complete the temperature mapping. Please see **Exhibit PSJ 4** for [redacted] walk-in-refrigerator ([redacted]) initial qualification protocol. Thereafter, the firm has conducted refrigerator re-mapping studies every 3 years, with the most recent re-mapping studies taking place in 2022. The firm used the same set of 16 thermocouple temperature probes (manufacture: Omega) for their original temperature mapping, and re-mapping activities. Mr. Anbu Devasahayam, President, stated that the firm conducted probe calibration using a single temperature traceable reference standard prior to use. Please see page 20 of 68, Exhibit PSJ 4 for the calibration work sheet. Mr. Devasahayam stated that the firm follows the same protocol during the temperature re-mapping process. For the recent re-mapping report for [redacted] please see **Exhibit PSJ 5.** The firm stated that they used the same initial qualification protocol and thermocouple temperature probes for all five refrigerators (Part No: [redacted]).

[redacted]

Discussion with Management:
During the daily wrap-up and closeout meeting, firm's management acknowledged our concern of not calibrating thermocouple temperature probes using standard calibration protocol to include the temperature use range. Mr. Sam Mullapudi, CEO, stated that the firm would respond to this observation in writing to the agency within 15 business days.

OBSERVATION 3

[redacted]

The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

a. Warehouse operators have not fully followed the SOP 6001.11, titled "Incoming shipment receipt procedure", effective date: 08/12/2024. Seven units were observed with handwritten lot numbers using a black marker in the quarantine refrigerator (Equipment ID [redacted]). Your firm's SOP doesn't allow handwritten labelling on incoming materials.

b. Warehouse operators have not fully followed the SOP 6004.10, titled "shipping/transfer procedures", effective date: 08/12/2024. The dispensed quantity has not been updated on the inventory label since 02/24/2025, for lot # [redacted] stored in the release refrigerator (Equipment ID # [redacted]). According to the reconciliation report, several dispense events for the above lot were conducted but not recorded on the inventory label nor notified to QA. Per SOP, material dispensing updates should be recorded on the inventory label, and any discrepancy should be reported to QA by the warehouse operators.

Reference: 21 CFR 211.22(d)
Supporting Evidence and Relevance:

a. The firm's warehouse incoming material SOP is governed by the SOP 6001.11, titled "Incoming shipment receipt procedure", effective date: 08/12/2024 (**Exhibit PSJ 6**). Under section V procedure, subsection F (page 3 of 4, **Exhibit 6**) of the SOP, stated that "Once the inspection is completed, print the sample label and inventory label. Affix the sample label and the inventory label on the package and store the product in the respective location". During the walkthrough of walk-in-refrigerator (Equipment ID [redacted] use to store quarantine materials, we observed that the warehouse operators had labeled 7 units of incoming materials with handwritten lot numbers using a black marker. Please see the pages 1 to 2 of 3 of photographs of handwritten lot numbers using a black marker in **Exhibit PSJ 7**. The page 3 of 3, photograph in **Exhibit PSJ 7** includes an approved label and inventory label per SOP 6001.

b. In Section VI procedure, subsection H of the SOP 6004.10, titled "shipping/transfer procedures", effective date: 08/12/2024 (**Exhibit PSJ 8**), stated that "The Technician shall handle one shipment at a time and complete the packaging of the shipment before processing the next shipment. Note: Update the Inventory label with Qty. removed. Notify QA about any discrepancy found, such as missed entry on the inventory label or Physical Inventory". During a walkthrough of walk-in-refrigerator ID # [redacted], we observed discrepancies with reported quantities on inventory label (**Exhibit PSJ 9**) and dispense activities reported in the inventory reconciliation report (**Exhibit PSJ 10**) of lot # [redacted]. QA was not notified about these discrepancies. For example: according to the inventory label (**Exhibit PSJ 9**) of Lot# [redacted], the last dispense was done in 2/24/2025 with 14 units issued and 199 units reported as balance. However, Lot# [redacted] inventory reconciliation report (**Exhibit PSJ 10**) stated that multiple dispense activities were completed 03/03/2025, 03/10/2025, 03/17/2025 and 04/31/2025, but these activities were not recorded in the inventory label (**Exhibit PSJ 9**).

Discussion with Management:
During the daily wrap-up and closeout meeting, firm's management acknowledged our concern of not following the SOP during the warehouse processes. Mr. Sam Mullapudi, CEO, stated that the firm would

[redacted]

respond to this observation in writing to the agency within 15 business days.

OBSERVATION 4
Written procedures are not drafted, reviewed and approved by the appropriate organizational units. Specifically,

Your firm doesn't have a written SOP detailing the handling of investigations, such as root cause analysis and CAPA effectiveness checks.

Reference: 21 CFR 211.100(a)
Supporting Evidence and Relevance:
The firm's complaint SOP is governed by SOP 2011.09, titled "customer complaint processing procedure", effective date: 10/29/2023 (**Exhibit PSJ 11**). The SOP, section IV procedure, subsection B and C (page 3 of 4, **Exhibit PSJ 11**) has instructions about handling investigations. The firm has another SOP, SOP 2013.06, titled "Corrective and Preventative Action (CAPA)", effective date: 11/27/2024, providing guidance on CAPA, risk analysis and root cause analysis (Section IV procedure, subsection B, C, D and E, pages 3 and 4 of 5, **Exhibit PSJ 12**). However, there is no written procedure to follow for performing any investigations, including finding root cause analyses, and checking CAPA effectiveness in these SOPs.

Discussion with Management:
During the daily wrap-up and closeout meeting, firm's management acknowledged our concern of not having SOPs detailing handling of investigations, such as root cause analysis and CAPA effectiveness checks for compliant investigations and deviations reviews. Mr. Sam Mullapudi, CEO, stated that the firm would respond to this observation in writing to the agency within 15 business days.

REFUSALS
No refusals were encountered during the inspection.

GENERAL DISCUSSION WITH MANAGEMENT
(Written by MOI)
At the conclusion of the inspection an FDA-483 was issued to Mr. Sombabu Mullapudi, CEO, who state he is the most responsible person for the firm. The following employees were present for the closeout meeting: Mr. Anbu Devasahayam, President, Mr. Arun Kantareddy, Vice President of Operations, Ms. Vijaya Rangavajhula, Vice President of QA/QC, Mr. Hemanth Sanagapati, Director of QA/QC, Mr. Raghuveera Yaramolu, Director of Packaging & Labeling, Mr. Raghavendra Motamarri, QA/QC Research Associate, Mr. Manoj Adusumilli, Vice President of IT / Global Operations and Mr. Rajashekar Pingali, Director of Manufacturing.

In addition to the observations described on the FDA-483, the following verbal observations were discussed with the firm during the course of the inspection as well as during the closeout meeting:

- Our review of multiple batch records revealed that the name and signature log was not included in the master and executed versions. Consequently, the lack of a signature log sheet hinders our ability to identify the specific employees involved in each stage of production.

During discussions with firm management, we raised concerns of not having a signature log attached to the batch records. Firm management acknowledged these concerns.

ADDITIONAL INFORMATION

(Written by PSJ)

All exhibits were sourced from USB Flash Drives provided by the firm. A USB flash drive containing documents electronically received from the firm is enclosed in sealed FDA 525 (**Exhibit PSJ 17**). A working copy of the USB flash drive is filed with the unlabeled exhibits. The original copy CD-R containing the photographs taken during the inspection officially sealed in Form FDA 525 (**Exhibit PSJ 18**) and the unsealed working copy CD-R are filed with attachments.

SAMPLES COLLECTED

No samples were collected during the current inspection.

VOLUNTARY CORRECTIONS

The firm's previous inspection, conducted 2/3/2020- 2/6/2020, did not result in the issuance of a Form FDA 483, Inspectional Observations

EXHIBITS COLLECTED

Exhibit	Pages	Document Description
Exhibit PSJ 1	05	[redacted]
Exhibit PSJ 2	09	
Exhibit PSJ 3	402	
Exhibit PSJ 4	68	
Exhibit PSJ 5	26	
Exhibit PSJ 6	04	
Exhibit PSJ 7	03	
Exhibit PSJ 8	08	
Exhibit PSJ 9	01	
Exhibit PSJ 10	02	
Exhibit PSJ 11	04	
Exhibit PSJ 12	05	
Exhibit PSJ 13	01	
Exhibit PSJ 14	40	
Exhibit PSJ 15	30	
Exhibit PSJ 16	01	General Organizational Chart
Exhibit PSJ 17		USB portable hard drive containing electronic documents provided

		by the firm_ enclosed in sealed FDA 525
Exhibit PSJ 18		CD-ROM of photographs taken during the inspection, sealed in a Form FDA 525

ATTACHMENTS

1. Form FDA 482, Notice of Inspection issue to Mr. Sombabu Mullapudi, CEO, EMINENT Services Corporation on 04/24/2025, 3 pages.
2. Form FDA 483, Inspectional Observations issued to Mr. Sombabu Mullapudi, CEO, EMINENT Services Corporation on 04/28/2025, 04 pages.

Pushpa S. Jayasekara -S Digitally signed by Pushpa S. Jayasekara -S Date: 2025.05.28 11:12:14 -04'00'

Pushpa S. Jayasekara
Investigator, OHADI 2

Michael O. Idowu -S Digitally signed by Michael O. Idowu -S Date: 2025.05.28 11:07:59 -04'00'

Michael Idowu
Investigator, OHADI 2

Azeezat M. Lawal -S Digitally signed by Azeezat M. Lawal -S Date: 2025.05.28 10:57:52 -04'00'

Azeezat Lawal
Investigator, OHADI 2