Department of Health and Human Services

Food and Drug Administration

Central Region
Baltimore District
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Baltimore, MD 21215
Phone: (410) 779-5455
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November 3, 2015

Dr. Krupakar Paul Thadikonda, President and CEO
Eminent Services Corporation
7495 New Technology Way
Frederick, Maryland, 21703-9401

Dear Dr. Thadikonda,

The U.S. Food and Drug Administration (FDA) conducted an inspection at 7495 New Technology Way Frederick, Maryland, 21703-9401, ending on August 14, 2015. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA releases a copy of the inspection report to the inspected firm.

You will find a copy of the FDA Establishment Inspection Report attached. FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you, or acknowledging that the state provided you a copy at the close of their inspection.

Please contact our office if you have questions.

Sincerely,

Constance Richard-Math
Director, Investigations Branch

Enclosure:
FEI: 3001701623

TABLE OF CONTENTS

SUMMARY

This surveillance inspection of a human drug repackager and relabeler was conducted in as part of the BLT-DO FY15 Drug Workplan in accordance with CP 7356.002B, "Drug Repackers and Relabelers" under FACTS Assignment ID #11469226 and Operation ID #7601348. The inspection covered Packaging and Labeling and Quality Systems.

The previous inspection was a directed pre-approval inspection and abbreviated GMP inspection conducted from 01/13/2010 – 01/15/2010, classified as NAI, and covered Packaging and Labeling and Quality Systems. No FDA-483 was issued to the firm as a result of the inspection. The following three (3) discussion items were discussed with the firm: (1) registration as a human drug repacker/relabeler; (2) update recall SOP; and (3) rotation of employees during packaging/labeling.

The current inspection revealed the firm continues to operate as a human drug repackager and relabeler in addition to performing operations for clinical trial drug products, including researching, manufacturing, repackaging, and relabeling. No FDA-483 was issued at the conclusion of this inspection. The following one (1) discussion item was discussed with the firm: completing thorough investigations of incidents and/or deviations to initiate CAPAs.

No samples were collected and no refusals were encountered.

ADMINISTRATIVE DATA

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
Website	www.emiserv.com
Dates of inspection:	8/12/2015, 8/13/2015, 8/14/2015
Days in the facility:	3
Participants:	LTJG James Michael Simpson, Investigator LCDR Chaltu N. Wakijra, Investigator

I, LTJG James Michael Simpson, Investigator, and LCDR Chaltu N. Wakijra, Investigator arrived at the firm, unannounced on 08/12/2015, presented our FDA credentials and issued an FDA 482, "Notice of Inspection," to Dr. Krupakar Paul Thadikonda, Ph.D., President & CEO **(See Attachment #1).** Dr. Thadikonda stated he was the most responsible person at the firm. An opening meeting was held at the firm on 08/12/2015 with Dr. Thadikonda, and Jhansi R. Kalluri, QA/QC Director. I explained the purpose of our visit a GMP inspection for any commercial products they handled.

On 08/14/2015 a closeout meeting was held with the following individuals present: Dr. Thadikonda, Mr. Anbu (Smiles) Devansahayam, Vice President, Mr. Hemanth K. Sanagapati, QA/QC Manager, Mr. Kalluri, Investigator Wakijra, and I. No FDA-483 was issued as a result of the inspection; however, one (1) item was verbally discussed at the firm **(See General Discussion with Management Section of this report).**

This report was written by Investigator Simpson (JMS) and Investigator Wakijra (CNW).

HISTORY (CNW)

The following information was provided to me by Dr. Thadikonda:

Eminent Services Corporation (herein after ESC) was established as an S-Corp in 1997 in Gaithersburg, MD. The goal of the firm was to provide companies with investigational drug management services. The firm expanded in 2000 and then moved to its current 57,000 sq. ft. location in Frederick, MD in 2002. Dr. Thadikonda provided us with a copy of the firm's site map **(See Exhibit #1).**

There have been no changes to major equipment or facilities since the last FDA inspection in 2010. The only major change to upper management since 2010 was the promotion of Mr. Devansahayam to Vice President in 2013.

ESC is currently registered in FACTS as a human drug repacker and relabeler. The firm's hours of operation are 8 A.M. to 5 P.M, Monday through Friday. The firm currently has 24 employees. The firm's establishment size is 6.

There is no history of regulatory actions regarding this firm. There have been no recalls of commercial products since the last inspection.

Post-inspectional correspondence should be forwarded to:

Eminent Services Corporation
ATTN: Dr. K. Paul Thadikonda, Ph.D., President & CEO
7495 New Technology Way
Frederick, MD 21703

INTERSTATE COMMERCE (CNW)

Dr. Thadikonda stated the firm only has [redacted] for which they package and label three (3) commercial products per SOP 0011-02.06 "Commercial Operations" (eff. date 01/09/2014) **(Exhibit #2).** ECS ships the finished commercial product to a [redacted]

JURISDICTION (CNW)

Dr. Thadikonda provided a list of all commercial products handled by ECS **(See Exhibit #3).** Currently, the firm handles three (3) commercial drug products (packaging and labeling only),

[redacted] which is approved for sale and distribution in the US. Based on the definition provided in the Food, Drug, & Cosmetic Act this product is considered a human drug and is therefore under the jurisdiction of the FDA.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (CNW)

Dr. Krupakar Paul Thadikonda, PHD. President and CEO

Dr. Thadikonda has been with the firm since 1998. He is the most responsible person at ESC. His responsibilities are: manages the firm operation, does hiring and firing of employees, public relations, and business proposals. Dr. Thadikonda was present for the inspection opening and closing meetings and was available through ought the inspection. Dr. Thadikonda has the power, responsibility, and authority to prevent, detect, and correct violations in the firm.

Mr. Anbu (Smiles) Devansahayam, Vice President

Mr. Devansahayam joined ESC in September 2003 as validation engineer and 2013 he was promoted to his current position as Vice President. His responsibilities include to manage the firm's overall operations and to oversee the IT department. Mr. Devansahayam indicated he has the power and authority to prevent, detect, and correct violations. Mr. Kantareddy reports directly to Dr. Thadikonda. He was present through ought the inspection to include opening and closing meetings.

Mr. Hemanth K. Sanagapati, QA/QC Manager

Mr. Sanagapati has been with the firm since 2003. He has been working in the quality department for the past 12 years and has been on his current position since 2005. He has power and authority to make changes in the following areas: packaging, labeling, shipping and receiving. , is responsible for overseeing the QA/QC department and has ESC's final release on all finished products. Mr. Sanagapati does not have the power and authority to hire and fire employees. He directly reports to Ms. Kalluri. Mr. Sanagapati was present throughout the inspection to include opening and closing meetings. Mr. Sanagapati provided pertinent information and records contained in this report

Jhansi R. Kalluri, MS, QA/QC Director

Ms. Kalluri has been with ESC since 2001 and she was promoted to her current position as QA/QC Director in 2009. She has power and authority to make minor changes. Ms. Kalluri does not have the power and authority to hire and fire employees. She reports to Mr. Devansahayam, VP. She was present throughout the inspection to include opening and closing meetings. Ms. Kalluri provided pertinent information and records contained in this report.

Dr. Thadikonda provided us with a copy of the firm's Organizational Structure **(See Exhibit #4).**

FIRM'S TRAINING PROGRAM (CNW)

I reviewed Eminent Services Corporation's Training SOP (# 5050.04). Eminent requires each staff member to receive trainings, including in-house, specialty, cGMP, hands-on training, and SOP review. Dr. Thadikonda informed me that each employee is required to take annual cGMP training. The employees are also given training specific to their duty area.

Upon review of the staff training files, some of the trainings include cGMP and QA/QC. Employees also receive job specific training, SOP review, facility, general, specialized as well as investigational drug repository training.

I reviewed a selection of five (5) staff members, which included employees working in QA/QC, Research and Packaging and Labeling. All the staff members reviewed received initial SOP training, facility, specialized training, and yearly cGMP training. I have no objectionable observations.

MANUFACTURING/DESIGN OPERATIONS (JMS & CNW)

Quality System

(CNW) Deviations/Incidents

I reviewed SOP 2012.07, "Deviation/Incident Report Processing" (eff. date 03/17/2013). Dr. Thadikonda provided a list of all Deviations/Incidents for the period of 01/01/2010 thru 12/31/2015. Investigator Simpson and I reviewed 15 deviations. I did not observe any deficiencies in the deviation/incident reports I reviewed.

Packaging and Labeling System

(CNW) Batch Records

Dr. Thadikonda provided us with a list of all production batches for the packaging and labeling 01/01/2010 and 08/12/2015. Investigator Simpson and I reviewed 15 Packaging and Labeling Batch Records [redacted].

(JMS) Receiving

Dr. Thadikonda walked Investigator Wakijra and me through the receiving process. He stated [redacted] products are received at the firms loading dock where the product label and quantity received is compared to the manifest. Once the inventory is complete the product is assigned a sample number and stored in one of two refrigerators (RT1 and RT2). At the time of receipt, or as soon as an Eminent employee is available, the product will be received into the Investigational Drug Management System (IDMS) system according to procedure 6001.05 "Incoming Shipment Receipt

Procedure" (eff. 05/14/2014). At the completion of inspection and upon entering the data into IDMS, a sample and inventory label is printed and affixed to the package. The information is reviewed by a supervisor and then filed until the product is sent for packaging.

Packaging components are received and inspected according to procedure 2003.07 "Packaging Components (Supplies) Inspection Procedure" (04/23/2013). A Receiving Inspection Report for Packaging Supplies is used to document the receipt and physical inspection of the packaging supplies. An IDMS part number is assigned to all packaging supplies. A sampling plan is provided in procedure 2003.06 providing the number of units to sample to ensure product meets the approved specifications. A sample label is affixed to the packages and a supervisor will perform a final check of the packaging material prior to product packaging.

All primary packaging supplies are received under quarantine, sampled, reviewed and approved upon receipt then stored in a locked room. QA/QC is authorized to release the primary packaging and perform an inspection followed by placing a released seal on each container of the primary packaging with their initials and date.

(JMS) Packaging and labeling

On 1/14/10 Investigator Wakijra and I observed a portion of the packaging and labeling of Eminent Lot# 2015R00492, 2015R00502, and 2015R00610. Components used in packaging and labeling follow requirements provided by [redacted] stated in the memo "Component Information" (dated 08/13/2015) **(Exhibit #5)**. During the process a total of five employees (one of which is the project manager) manually label the product and package it into cartons. The batch was packaged in multiple portions to ensure the product was never out of refrigeration for longer than two hours. The packaging/labeling process we observed is a follows:

Two employees pull the boxes containing product to be packaged from a specific refrigerator shelf, whose location is identified by the shelf ID# stated on the packing slip → The boxes are placed on a cart and opened in the refrigerator → the product is counted to ensure all product to be packaged and labeled in present → the boxes are retaped close and kept on a cart in the refrigerator → A second cart containing the batch records and labels/packaging materials are brought into the Pack & Label Room from the locked adjacent room → Room clearance and batch issuance is performed by QA → the cart with product is wheeled into the Pack & Label Room from the refrigerator → QA checks to make sure the lot# and sample ID # on all the boxes are correct → The cart is placed back into the refrigerator → One box is taken into the room to be packaged and labeled → the first employee wipes the naked vial of any moisture → A second employee applies the label → A third employee does a visual inspection to ensure the label is straight and the vial lot #/exp date and Baxter lot # are correct and then places the vial in the carton (which a 4th employee is folding together) with the instructions → A fifth employee (project manager) places the finished product into a cardboard tray → Once all vials in the box have been packaged and labels the box is brought back to the refrigerator and placed on a different shelf according to the shelf id # in the packing slip → A second box of naked vials is brought to the Pack & Label Room and the process starts anew → Once all 1500 vials

have been packed and labeled they are placed back in the refrigerator → QA reconciles the number of leftover labels and cartons → All extra packaging/labeling materials are defaced and placed in the locked shred box.

(JMS) Labels and Labeling Control

Dr. Thadikonda stated labels for bulk packaging are stored in a locked room. [redacted] only ships released components already inspected to Eminent. Upon receipt at Eminent the label is re-inspected according to ESC procedures and stored in a locked room. Dr. Thadikonda stated the label printing process is initiated once an approved label request with sample ID is received. The values are entered into the label printer.

MANUFACTURING CODES (CNW)

All documented operations at ECS are given a unique identifying code, including Packaging/Labeling Batch Records, Deviation Reports, Client Complaints, Outgoing Shipments, and Incoming Receipts. The basis for the codes is as follows:

Four digits of year – capital letter indicating type of operation – four digit sequential event*

*shipping and receiving records use five digit sequential events

Examples:
2009B0234 = 234th Packaging/Labeling Batch Record created at ECS in 2009
2008C0012 = 12th Client Complaint received at ECS in 2008

The firm combines all products (commercial and clinical) when sequentially numbering their packaging/labeling batch records.

Letter Indicating Codes:
B = Packaging/Labeling Batch Record
D = Deviation
C = Complaint
S = Shipped
R = Received

COMPLAINTS (CNW)

I reviewed ESC's formal written customer complaint SOP # 2011.06, "Customer Complaint" (eff. date 04/01/2011). The document outlines the steps and procedures to be followed when handling complaint. Information about the complaint is manually entered into the system, with an audit trail, and the record is given a unique number. All customer complaints are entered into the firm's Corrective Action/Preventive Action (CAPA) system. QA will track and trend the complaints from the log and reports at the firm's monthly QA meeting. I reviewed Customer Complaint #2015C009 (electronic), dated 03/30/2015. There were no deficiencies to report.

RECALL PROCEDURES (CNW)

Dr. Thadikonda stated the firm has never had to perform a recall on a commercial product. I reviewed SOP 6013.05 "Drug Product Recalls" (eff. date 10/20/2014). ESC does not perform recall operations of [redacted] products. I have no objectionable observations.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (JMS)

No FDA-483 was issued as a result of this inspection.

REFUSALS (CNW)

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT (JMS)

On 08/14/2015, Investigator Wakijra and I held a closeout meeting with the following individuals present: Dr. Thadikonda, Mr. Sanagapati, Mr. Kantareddy, and Ms. Kean. Investigator Rose was not present during the closeout meeting.

No FDA-483, "Objectionable Conditions" was issued to the firm as a result of this inspection; however, the following one (1) item was verbally discussed with the firm:

1. *Completing thorough investigations of incidents and/or deviations to initiate CAPAs.* I explained to Dr. Thadikonda that after determining an incident or deviation occurred, the firm must thoroughly document the root cause and any corrective or preventative actions taken to prevent the incident from occurring in the future. In addition, an effectiveness check needs to be conducted to see if the CAPA was successful or not.

ADDITIONAL INFORMATION (CNW)

No additional information

SAMPLES COLLECTED (CNW)

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS (CNW)

No FDA-483 was issued during the previous inspection in January 2010.

EXHIBITS COLLECTED

1. Eminent Services Site Facility Map (no date, 1 page)
2. SOP 0011-02.06 "Commercial Operations" (01/09/2014, 13 pages)
3. Eminent Services Products Repacked (08/14/2015, 1 page)
4. Eminent Services Organizational Chart (08/14/2015, 1 page)
5. [redacted] Component Information Memo (08/13/2015, 2 pages)

ATTACHMENTS

1. A FDA-482 "NOTICE OF INSPECTION" issued to Mr. Krupakar Paul Thadikonda, President and CEO, dated 08/12/2015 (2 pages, double-sided)

James Michael Simpson

LTJG James Michael Simpson, Investigator

LCDR Chaltu N. Wakijra, Investigator