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SUMMARY

[SGD]

This unannounced, comprehensive, current good manufacturing practices (cGMP) surveillance inspection of drug repackager and relabeler, and a contract non-sterile, prescription, for human use, oral dosage finished drug products manufacturer was conducted per an Office of Regulatory Affairs (ORA), Division I fiscal year 2020 workplan assignment. The scope of the inspectional assignment was to provide surveillance coverage for repackaging and relabeling of commercial products for the U.S. market. Inspectional guidance was provided by Compliance Programs 7356.002B, *Drug Repackagers and Relabelers*, and 7356.002, *Drug Manufacturing Inspections*. This inspection is reported under [redacted]. Inspectional coverage was for the profile codes SVL – small volume parenterals (lyophilized), and SVS – sterile-filled small volume parenteral drugs.

The firm's previous U.S. FDA drug inspection was a cGMP surveillance inspection conducted August 12 – 14, 2015, and was classified as "no action indicated" (NAI). Systems-based inspectional coverage was provided for the packaging and labeling, and quality systems. A Form FDA 483, *Inspectional Observations*, was not issued. There was one verbal observation regarding completing thorough investigations of incidents and/or deviations to initiate corrective and preventive actions (CAPAs).

The current inspection provided coverage for the quality, facilities and equipment, packaging and labeling, and production systems. Coverage was not provided for the materials and laboratory control systems. Inspected products included [redacted] under the SVL and SVS profile classes. Documentation review included batch production records, standard operating procedures (SOPs), deviation investigations, customer complaints, and equipment maintenance records. A Form FDA 483, *Inspectional Observations*, was not issued. One verbal observation was discussed with management regarding the lack of drafting and reviewing proposed changes to procedures and facilities. The firm's management committed to providing the agency a voluntary written response within 15 business days.

No refusals were encountered. No samples were collected.

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
Dates of inspection:	2/3/2020-2/6/2020
Days in the facility:	4
Participants:	**Sena G Dissmeyer, Investigator** **Adam Derr, Ph.D., Microbiologist**
Website:	www.emiserv.com

[SGD]
On February 3, 2020, Microbiologist Adam Derr, Ph.D., a Center of Veterinary Medicine (CVM) review microbiologist, and I, Investigator Sena G. Z. Dissmeyer, presented our FDA Official Credentials and issued a Form FDA 482, *Notice of Inspection* (**Attachment 1**), to Mr. Krupakar P. Thadikonda, Ph.D., Director of Board, who identified himself as the most responsible person of the firm. We opened the inspection with a brief introduction and explained that the purpose of the inspection was for current good manufacturing practices surveillance coverage of repackaging and relabeling operations of commercial products for the U.S. market.

Post-inspectional correspondence should be addressed to:

Mr. K. Paul Thadikonda, Ph.D., Director of Board
Eminent Services Corporation
7495 New Technology Way
Frederick, MD 21703-9401
PThadikonda@emiserv.com
Mobile phone: 301-674-8066

No other government agencies or in-plant inspectors were present. Microbiologist Derr was present for all portions of the inspection except for the morning of February 5, 2020. I, Investigator Dissmeyer, was present for all portions of the inspection.

This report was written by both of us. The author of each section is identified by bracketed initials – [SGD] for sections I, Investigator Dissmeyer, wrote, and [AD] for sections Microbiologist Derr wrote.

Dates written in the formats DD/MM/YY, DD/MM/YYYY, or DDMMMYYYY were taken from firm documentation.

HISTORY

[SGD]

Since the August 2015 inspection, the firm has ceased repackaging and relabeling operations of [redacted] for the U.S. market, decommissioned the respective master batch records, renovated the facility with a new roof and heating, ventilation, and air conditioning (HVAC) system in 2017, and has made personnel changes. Mr. K. Paul Thadikonda, Ph.D., previously the President and Chief Executive Officer, has retired from his daily duties as of 2019 and is now the Director of Board. As of January 1, 2019, Mr. Anbu Devasahayam was promoted from the Vice President of Administration to President. Also, Ms. Jhansi Kalluri, previously the Quality Assurance/Quality Control Director, left the firm in approximately August 2016. As of October 2016, Ms. Vijaya Rangavajhula is the Vice President, Quality Assurance.

Mr. Arun Kantareddy, Vice President, Operations, provided an opening presentation regarding the firm's history and overview of their "Investigational Drug Management System" (IDMS). The firm was founded as a small business corporation ("S-corp") in 1997, incorporated in Maryland, to provide investigational drug management services to sponsors. Mr. Thadikonda explained that the board of directors is a one-person board, himself, to which the president reports. There are no corporate or subsidiary organizations.

The firm does not have a violative inspectional history. According to Mr. Thadikonda, on February 3, 2020, the firm has never had any recalls or field alert reports.

The firm's business hours are from 8:00 AM to 5:00 PM, Monday through Friday. Per Ms. Rangavajhula, Vice President, Quality Assurance, the firm has approximately 23 employees. This is a decrease of one employee, as previously reported in the August 2015 establishment inspection report.

The firm's drug re-registration status is current for 2020.

Post-inspectional correspondence should be addressed to:

Mr. K. Paul Thadikonda, Ph.D., Director of Board
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Mobile phone: 301-674-8066

According to Mr. Devasahayam, the firm has one customer for commercial products. He explained that all commercial products are produced for [redacted] (acquired by [redacted]) and are shipped to [redacted]. Additionally, he explained that they have contracts with various government entities and provided a list of those customers (**Exhibit 1**) which include the National Institutes of Health (NIH), the National Institute on Drug Abuse (NIDA), and the National Institute of Allergy and Infectious Diseases (NIAID). He explained

that they provide compassionate use mail-order pharmacy operations to support drug management; they do not operate a general open pharmacy and do not perform compounding operations.

INTERSTATE (I.S.) COMMERCE

[SGD]

Management provided a copy of the bills of lading (BoL), packing slips, and associated certificates of analysis (CoA) for the following shipments from the firm located in Frederick, Maryland to [redacted]

- [redacted]
- [redacted]

According to Mr. Anbu Devasahayam, President, the firm's gross annual sales in 2019 were in the [redacted] to [redacted] range, with approximately [redacted] products sold in interstate commerce. While there are no longer sales of repackaged/relabeled commercial products for the U.S. market, he estimates that approximately [redacted] is due to [redacted] products for the international market. The remainder of revenue is generated through investigational drug management and consulting services.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

[SGD]

Mr. Anbu Devasahayam, President, explained that the firm contract repackaged/relabeled two commercially approved [redacted] for the U.S. market, [redacted]. However, they have ceased repackaging/relabeling operations for the U.S. market and have decommissioned the master batch records at the sponsor's request. They continue to repackage/relabel the same products for international markets under different master batch records. Additionally, they manufacture investigational drug products.

For the [redacted]. He provided a report (**Exhibit 4**) from their IDMS inventory system indicating that the last batch of [redacted] was received in [redacted]. It was repackaged/relabeled and shipped by the firm in [redacted]. The expiry of this lot is [redacted]. Additional lots within expiry as of the close of this inspection are presented in the report. Management explained that [redacted]. Similarly, the latest expiry batch of [redacted] was received and repackaged/relabeled in [redacted]. One batch was received in [redacted] but expires sooner, [redacted]. The master batch records were authorized to be obsoleted in [redacted] and [redacted], respectively.

Previously, the firm packaged another product for the U.S. market. Mr. Arun Kantareddy, Vice President, Operations, showed me that the last batch of [redacted] was packaged by the firm on [redacted]. Additionally, the firm imported for export another product, [redacted], but does not perform any U.S. commercial distribution.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

[SGD]

Since the August 2015 inspection, the firm has made personnel changes. Mr. K. Paul Thadikonda, Ph.D., previously the President and Chief Executive Officer, has retired from his daily duties as of 2019 and is now the Director of Board. As of January 1, 2019, Mr. Anbu Devasahayam was promoted from the Vice President of Administration to President. Also, Ms. Jhansi Kalluri, previously the Quality Assurance/Quality Control Director, left the firm in approximately August 2016. Ms. Vijaya Rangavajhula was onboarded as the Vice President, Quality Assurance in October 2016.

Ms. Rangavajhula provided an organization chart (**Exhibit 6**).

Mr. Krupakar Paul Thadikonda, Ph.D., Director of Board, has "retired" from daily duties as President and Chief Executive Officer. However, he comprises the one-person board of directors, manages overall company performance, assists as a staff pharmacist, assists with formulation development and regulatory affairs, and is the most responsible person of the firm with ultimate hiring and firing authority of employees. He stated that he has the duty, power, responsibility, and authority to prevent, detect, and correct violations at the firm. He was present during the opening meeting, daily wrap-up meetings, intermittently during documentation review, and the closeout meeting. He provided information regarding the firm's structure and responses to discussed deficiencies.

Mr. Anbu S. Devansahayam, MS, President, 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 indicated he has the power and authority to prevent, detect, and correct violations. He has the authority to hire and fire employees. He reports directly to Mr. Thadikonda. Mr. Devansahayam was present throughout the inspection to include the closeout meeting.

Ms. Vijaya L. Rangavajhula, Vice President, Quality Assurance, has been with the firm since October 2016. Her responsibilities include leading the quality unit, revising standard operating procedures (SOPs), manage deviations, internal audits, complaints, training, and making changes to batch records based on sponsor provided and internal justification. She does not have the authority to hire and fire employees. She reports to Mr. Devansahayam. Ms. Rangavajhula was present throughout the inspection to include the opening, daily wrap-up, and closeout meetings, walkthrough inspections, and documentation review. Ms. Rangavajhula was our main source for providing requested documentation and information pertinent to the quality system.

Mr. Arun Kantareddy, Vice President, Operations, 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 directly or indirectly supervises approximately 14 employees. He does not have the power and authority to hire and fire employees. He reports to Mr. Devansahayam. Mr. Kantareddy was present during the daily wrap-up meetings, during documentation review, and the closeout meeting. Additionally, he provided an overview presentation regarding the firm's history and IDMS.

Mr. Hemanth K. Sanagapati, Quality Assurance/Quality Control Manager, has been with the firm since 2003 and in his current position since 2005. He has power and authority to make changes in the following areas: packaging, labeling, shipping and receiving. 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. Mr. Sanagapati does not have the power and authority to hire and fire employees. He directly reports to Ms. Rangavajhula. Mr. Sanagapati was present intermittently during documentation review.

FIRM'S TRAINING PROGRAM

[SGD]

We reviewed SOP 5050.07, entitled *Employee Training*, effective 17Apr2018. We observed that the revision history for the recent changes to the SOP included a new checklist and clarification for reading revised SOPs. Per the procedure, there is new employee orientation, internal and external hand-on training, and SOP training. New employees are trained according to duties described in their respective job description through presentations, handouts, and SOPs. Training is recorded on form 052, *Training Record*. GMP training is required during initial training and accomplished through watching a video; thereafter, it is performed annually through presentations on pertinent, current topics with recent examples of deviations, as Ms. Vijaya Rangavajhula, Vice President, Quality Assurance, explained. Procedure step A.5.b states, "QA/QC Manager will allocate the SOP's pertaining to the employee. The employees will be notified through the Intranet system and email (if needed) regarding the pending SOPs to be read." We discussed with Ms. Rangavajhula that there is no training requirements matrix or list of SOPs required per job description or title. Mr. Paul Thadikonda, Director of Board, added that each operation will have its own procedures, so a new employee in that area will be assigned all SOPs in that respective section (**Exhibit 7**). Furthermore, employees are cross-trained by performing training in rotations of departments in order to train on other SOPs.

We reviewed the training records for Mr. S.B. Kalapala (a Research Associate who performs labeling operations at times), Mr. R.P. Yaramolu (Director of Packaging and Labeling, who performs the production manager review of batch records), and Mr. J.K. Manthena (Programmer, who is responsible for label printing). We observed cGMP training records dated 28Jul2017, 13Jul2018, and 20Aug2019 in which all three had signed the training log. Additionally, we observed each had training on the client-specific SOPs for which they performed activities and internal procedures such as deviation handling.

MANUFACTURING/DESIGN OPERATIONS

[SGD]

Since the August 2015 inspection, the firm has ceased repackaging and relabeling operations of Elaprase and [redacted], decommissioned the respective master batch records, and renovated the facility with a new roof and heating, ventilation, and air conditioning (HVAC) system in 2017.

Mr. Anbu Devasahayam, President, explained that the firm contract repackaged/relabeled two commercially approved prescription sterile finished drug products, for the U.S. market, for one customer, [redacted] was last repackaged/relabeled and shipped by the firm in [redacted]. [redacted] was last repackaged/relabeled in [redacted] with a lot expiry of [redacted]. The master batch records were authorized to be obsoleted in [redacted] and [redacted], respectively. The firm perform repackaging/relabeling of the commercial products for foreign markets, and investigational new drug operations for the U.S. market.

QUALITY SYSTEM

[SGD]

I reviewed the [redacted] (APQR) for January 2018 through December 2018, approved 01/10/2019. In this review period, there were 53 commercial batches packaged and released, one batch not for human use, and one de-labeling batch. Mr. Arun Kantareddy, Vice President, Operations, explained that the de-labeled batch was at the client's request because after labeling and documentation review by the client, they requested that the firm label the vials with a 24-month expiry rather

than a 36-month expiry for the [redacted] market (the client did not provide a memo originally requesting this change so the firm defaulted to the expiry noted on the CoA). There were six deviations, of which the root cause was client responsibility for four, one due to personnel negligence, and one pending for client input, all of which they determined have no impact on product quality. There were four customer complaints discussed in the APQR but not provided earlier upon our request for customer complaints. Mr. Kantareddy showed me that the complaints were for other markets, thus were included in the APQR but not provided earlier for our review. I discussed the content of these four complaints with Mr. Kantareddy and Ms. Vijaya Rangavajhula, Vice President, Quality Assurance. There were no recalls, returns, or change controls. The APQR also presented the equipment qualification status, follow-up from the previous year's review (which there were no items), and stated the latest technical quality agreement is on file. The distribution states the report is shared with the client. [redacted]

Similarly, I reviewed the [redacted] for January 2017 through December 2017, approved [redacted]. Ms. Rangavajhula explained that there was not a reason for the "delay" as compared to the 2018 report approved in January 2019; [redacted] requests the report by the end of March. In this review period, there were 64 commercial batches packaged and released, and one batch not for human use. There were five deviations and one customer complaint. The complaint originated from a pharmacy which was not in the firm's distribution chain, and the client accepted responsibility to further investigate. There were no recalls, returns, or change controls.

I reviewed the [redacted] for July 2018 through [redacted]. Corrections were made to correct typographical errors and the report was signed for approval again on [redacted]. I observed that the review included additional categories such as starting material and critical in-process controls; Ms. Rangavajhula explained that the format is dictated by the client each review cycle upon receipt of the APQR memorandum. During the review period, there were 24 commercial batches packaged and released, including two batches not for human use, five customer complaints, and one deviation. The deviation root cause was identified as client responsibility and deemed it had no impact on product quality. The five customer complaints were due to broken vials at the point of administration. Again, the root cause was determined to be client responsibility. There were no recalls, returns, or change controls.

Similarly, I reviewed the [redacted] for [redacted]. Corrections were made to move superscript notations from one column to another in a table discussing deviations; however, information was not added or deleted from the originally presented text. The corrections and report approval were dated 08/08/2018. During the review period there were 56 commercial batches packaged and released. There were three batch records which noted a yield below the 100% specification. The first is referenced in a deviation investigation regarding one vial that was broken during packaging. For the other two, a chipped vial each was found during production and set aside for customer notification. There were no customer complaints and nine deviations, all of which were deemed to have no impact on product quality. The root cause was attributed to client responsibility for five, and human error for four. There were no recalls, returns, or change controls.

I reviewed SOP 2012.09, entitled *Deviation/Incident Report Processing*, approved 04Dec2017. Per the procedure, QA/QC reviews procedures, forms, and record for compliance with firm procedures and cGMPs. Any deviations, including planned and unpanned, are documented on a *Deviation/Incident Report* form 055C through IDMS. The system generates a unique nine-character identifier represented by the four-digit year, a "D," and a sequentially assigned four-digit number restarting at 0001 each year. The operations manager determines the probable cause if there is an apparent cause. Investigation details are documented within

IDMS. QA/QC reviews and approves the deviation within 30 business days unless delayed by client input. Respective clients are notified if client products are involved in the deviation. Upon approval, the form is printed, initialed, and filed as the completed record.

We reviewed the *Deviation/Incident Log* (**Exhibit 8**) from 08/01/2015 through 02/03/2020. For the U.S. commercial market, there were four deviations in 2015, four in 2016, three in 2017, and five in 2018, for a total of 16. Issues included an extra carton found during reconciliation, receiving documentation errors, in-transit temperature excursions, a broken vial, and a missing line clearance.

I cross referenced the provided list of deviations against the [redacted] and [redacted] and [redacted]. I observed one deviation which was not presented in the APQRs but was in the provided list of deviations. Mr. Anbu Devansahayam, President, explained that Deviation [redacted] was regarding a product for the [redacted]. I observed the deviation and no observations were noted.

We reviewed the following deviations without observation:

- Deviation 2015D0089, initiated 09/03/2015, regarding the finding of one extra carton during reconciliation of batch 2015B0272. There were 5270 cartons issued to the batch, and the investigation found that likely 5271 were issued. The reconciliation was 100.02%, rather than 100% per specification. The carton was destroyed in the presence of quality assurance. Retraining was provided. The coding technicians were instructed to count 100% of cartons at the time of pulling them from inventory and performing the coding activity. We observed a copy of the training record for two employees dated 09/14/2015. The deviation was completed, reviewed and approved on 09/09/2015. The client also approved the deviation the same day. We noted to Ms. Rangavajhula that the training date was after the deviation closing date. We discussed that the tracking mechanism needs to ensure the corrective and preventive actions are completed before deviation closure, if the deviation itself is the tracking mechanism and a separate action is not created, which was the case.

- Deviation 2016D0059, initiated 05/23/2016, regarding a wrong sample identification label placed on one of the core boxes. Ms. Rangavajhula explained that the sample number was only for internal tracking purposes and it is not regarded as "labeling." The identified root cause was personnel negligence. Management explained that it is possible that a label was left over on a printer and when the label for the next shipment was printed, there was one extra on the roll. The technician who affixed the labels to the core boxes did not report the extra label to the supervisor, but rather discarded it. The corrective action was to verify all the core boxes for accuracy. They removed the wrong sample identification from the core box and printed one sample label with the correct sample identifier. Preventive actions included instructing the technicians printing and checking the labels to print only the exact number required and not leave any at the printer. Also, they need to verify the correct printer is selected to ensure there are no extra labels printed to an alternate location.

- Deviation 2017D0045, initiated 09/29/2017, regarding a missing line clearance entry for Line 2 during batch 2017B0230. The room was cleared prior to the production and clearance was documented on batch record page 16. Line 1 was cleared on page 4 of the batch record, but Line 2 was documented as “N/A.” Both lines were used according to batch record page 5. According to the investigation, both production lines were in the same room and used for the same product. The root cause was identified as personnel negligence. Personnel were reminded of data entry practices and the missing entry was corrected with reference to this deviation. The deviation was completed,

reviewed and approved by the quality unit the same day, 09/29/2017. The client reviewed the deviation on 02Oct17.

- Deviation 2017D0056, [redacted] batch record 2017B0287, initiated 12/22/2017. One vial was broken during packaging. The client was notified the same day that during packaging and labeling, one vial accidentally slipped off and broke while unloading from the box. The production area was cleaned, and the vial's remnants were sent for destruction. The batch yield was short by one vial. The root cause was assigned as personnel negligence. The deviation was completed on 12/28/2017, reviewed on 01/02/2018, and approved on 01/03/2018.

- Deviation 2018D0006, regarding an incorrect quantity of vials upon receipt. The firm noticed that one box was not marked as "partial" by the vial manufacturer. Full boxes contain 90 vials; however, one box was received with 78 vials but did not have an indication that it was not a full box. The client authorized the correction to 78 through email.

- Deviation 2018D0012, initiated 03/09/2018, regarding the firm finding one vial crimp with a defective ink-jetted lot number (the inkjet lot number on the crimp is performed by the manufacturer), and finding one vial was missing in a tray for batch 2018B0068. The vial with the defective lot number printed on the crimp was quarantined and reconciled with the client. The reconciliation yields reflected the issued and finished number of labeled vials.

- Deviation 2018D0051, initiated 10/01/2018, regarding the receipt of nine boxes labeled with a manufacturing date of 07/24/2018 and one box labeled with a manufacturing date of 07/25/2018. The lot was received into quarantine status and the firm notified the client of the discrepancy. The client provided a memorandum dated 01/15/2019 releasing the lot for use with the 07/24/2018 date. The deviation was completed, reviewed, and approved on 01/15/2019. Management explained that the deviation report indicates this lot as for U.S. distribution while in fact it was for the Mexican market. The discrepancy arises from the product for Mexico using the same insert as for the U.S. market, thus reflecting in the system as for U.S. distribution. Furthermore, the deviation was approved and the lot was used in 2019 after the U.S. commercial production was completed in November 2018.

- Deviation 2018D0054, regarding an incorrect entry of the product expiry into the system because the date provided by the client is written in the format month and year whereas the firm adds a day field. In this case, the expiry from the client was "May21," and for the day entry the firm's technician picked 30 rather than 31 by mistake as the last day of the month. However, the date in the system is not utilized for any GMP documentation and it is for reference purposes only. It was noticed during the process of initiating the batch record because the packaging and labeling department was checking all the accompanying paperwork and wanted to ensure the date in the system was updated, so a deviation was initiated. The entry was corrected.

- Deviation 2018D0059, regarding a material number on the product label not matching the material number on the CoA. The firm identified the discrepancy upon incoming receiving inspection. The root cause was assigned as client responsibility. The client issued a memorandum instructing to use the material number found on the CoA.

Ms. Rangavajhula provided the obsolete master batch records (MBR) for the two commercial products. I observed a memorandum (**Exhibit 5**, page 2) from [redacted] authorizing the firm to obsolete a list of clinical and commercial products including [redacted] I also observed the

Documentation Revision Control Record, form 24C.04, which indicates that revision history as follows: MBR [redacted] made effective 04/02/2018, made inactive 09/28/2018, and made obsolete 09/29/2018. She explained that according to their procedure, they must inactivate the document first before it can be obsoleted. Finally, I observed that the *Packaging/Labeling Batch Record* for material [redacted], the MBR, was marked as obsolete on the first page.

I observed a memorandum (**Exhibit 5**, page 1) from [redacted] authorizing the firm to obsolete the [redacted]. I also observed the *Documentation Revision Control Record*, form 24C.04, which indicates that revision history as follows: MBR 5000016.05 made effective 09/27/2018 and made obsolete 11/20/2018. She explained that between the obsoletion of the [redacted] MBRs, there was a change in the process in which the MBRs were no longer visible in the IDMS, thus obsoletion was done manually (and did not need to be inactive before obsolete). Finally, I observed that the *Packaging/Labeling Batch Record* for material 5000016, the MBR, was marked as obsolete on the first page.

I reviewed a *Technical Quality Agreement relating to Clinical and Commercial Drug Product Labelling and Packaging*, executed between [redacted] and Eminent Services Corporation, revision 5, originally signed February 16, 2016, and the latest addendum signed April 17, 2018. Ms. Rangavajhula explained that the quality agreement needs to be updated and that they have been communicating with the client in order to revise the list of products and personnel contact information to reflect the new [redacted]. According to the quality agreement, [redacted] is responsible, amongst other duties, for final product review and disposition, supplies, and shipping qualification. The firm is responsible, amongst other duties, for having procedures describing operations such as receipt, storage, labeling, cleaning, identification, and records on-site; notifying the client of deviations; providing the client an APQR after the client requests it with a specific due date and format; and notifying the client of any changes that may impact the site master file. Any commercial product rework requires the approval of the client.

Previously, they also had a quality agreement with [redacted], a wholly owned subsidiary of [redacted] dated September 7, 2005, but no longer have business with that subsidiary.

We reviewed change request 2017RQ0001, initiated 06/13/2017, regarding the replacement of the roof and HVAC system. According to Mr. Paul Thadikonda, Director of Board, the HVAC was a like-for-like replacement with the same brand and model. It was installed on 08/18/2017. On February 5, 2020, we discussed with Mr. Devansahayam, Ms. Rangavajhula, and Mr. Kantareddy that the *Change Request* does not capture all of the actions that may affect quality such as updating the preventive maintenance schedule, and detailing how many seasons would be included in the warehouse temperature mapping study. This was also discussed during the inspection closeout meeting (See the *General Discussion with Management* section, **Item 1**, below). The change control was approved for implementation on 06/22/2017. We observed that the temperature mapping study was approved on 12/8/2017. The change request was completed and closed on 05/21/2018.

PRODUCTION SYSTEM

[SGD]

Per the August 2015 establishment inspection report, there was one procedure, SOP 0011-02.06, [redacted], effective 01/09/2014, which detailed the firm's commercial packaging and labeling operations. I observed that the SOP was made "inactive" on 06/19/2017. According to Mr. Kantareddy, the firm continues to have only one client for which they perform packaging and labeling operations for commercial products; however, the procedure has been broken into five individual SOPs, with the respective version 00 for each

made effective on 06/19/2017, as follows:

- SOP 0011-06.01, entitled [redacted], approved 20June2018, effective 27Jun2018. According to the procedure, upon receipt of product from the client, the components shall be checked for part numbers against the written notification from the customer, the seals are checked against documentation, quantities are verified, and temperature monitoring will be verified. Then, the received product is moved to the temporary 2-8°C storage area. All unlabeled product is kept under quarantine status. The client's CoA is formatted as month and year, whereas the firm assigns the expiry as month, last day of the month, and year. For printed packaging components, the client releases all materials and sends them to the firm for use; the firm does not release packaging components, however, the firm will verify the lot number on each box label. These items are stored in a secure location with limited access privileges.

- SOP 0011-07.00, entitled [redacted], approved 16Jun2017, effective 19Jun2017. Per the procedure, the client is responsible for developing shipping qualifications and providing the pack-out configurations to the firm. "Temptales" are used to monitor the product temperature during shipment. The procedure also contains specifications for stacking core boxes on pallets, inspection of the truck and driver's identification, and associated documentation such as the bill of lading.

- SOP 0011-08.00, entitled [redacted], approved 16Jun2017, effective 19Jun2017. Per the procedure, the firm drafts the label template for a new product, and it is reviewed for approval by the client. Labels and cartons are qualified per a protocol and submitted to the client for approval. Ms. Rangavajhula explained that this process, for example, prints approximately 25 labels in order to verify that there is no shift in the printing area of the lot and expiry when a roll of labels is thermally printed. The client provides a purchase order and certificate of analysis for each drug product to be packaged by the firm. The quantity and lot number are derived from the CoA. For [redacted] while the expiry is 36 months, for some markets, the expiry is shortened to 24 months. As such, the client provides a memorandum with the purchase order when the expiry differs from the CoA, for example when packaging for the [redacted] market. The project manager explained that for the U.S. market, it is a 36-month expiry as of 23Sep16, and the client provides their specification with the expiry list per country (the firm does not create an internal specification). The procedure defines the label and carton printing font type, pressure, and size. Following printing and labeling operations, the firm sends the executed batch record to the client for review and approval. If any rework is needed, the firm drafts a batch record for client approval.

- SOP 0011-09.00, entitled [redacted], approved 16Jun2017, effective 19Jun2017. Per the procedure, if there are in-transit delays, the firm shall notify the client and the client can authorize return of the shipment to the firm. Upon receipt, it is handled as a new receipt and follows the standard receiving procedures with a new sample number assigned to the received product. Mr. Kantareddy explained that they have not had any returns for commercial product.

- SOP 0011-10.01, entitled [redacted], approved 20June2018, effective 27Jun2018. Per the procedure, changes to the mater batch records, packaging and labeling, and procedures must be approved in writing by the client and the firm. I observed that the remainder of the procedure mirrors the technical quality agreement with the client, delineating responsibilities for

the quality system. For example, the procedure states that the client will inform the firm in the event of a recall.

Management provided flowcharts which provide an overview of each major operation (**Exhibit 9**).

Furthermore, Mr. Kantareddy explained that before issuance, the cartons and labels printed in-house are counted and verified 100%. During packaging and labeling operations, there is a minimum of four personnel present. One person wipes the vials, another performs labeling and checking the crimp, another folds cartons and adds the insert with the vial into the primary carton, and another checks the label and ensures the carton contains the vial and insert. For some foreign markets, they apply an additional seal on the carton which is checked by a fifth person, but this is not used for the U.S. market.

Ms. Rangavajhula stated that the revision of the SOPs was pending, as of the close of the inspection, to reflect the client name change from [redacted]. They are waiting for a client response regarding the technical quality agreement and SOP revisions and discuss it with the client during their bi-weekly meeting.

FACILITIES AND EQUIPMENT SYSTEM

[SGD]

The firm occupies approximately 57,000 square feet in a two-story building, with walk-in refrigerators, standing freezers, storage area, a manufacturing area, laboratory, label printing and storage areas, and office space (**Exhibit 10**). The manufacturing area is divided into two sections – one a suite for contract production of non-sterile drug products, and the other containing rooms for contract repackaging and relabeling. We performed a walkthrough inspection of the incoming shipment area, walk-in refrigerators, general warehouse storage, label printing and storage areas, and repackaging and relabeling areas on February 3, 2020. We did not perform a walkthrough inspection of the laboratory. There were no active repackaging and relabeling operations.

The firm renovated the facility with a new roof and heating, ventilation, and air conditioning (HVAC) system in 2017. Mr. Kantareddy explained that they have not had power outages lasting longer than half an hour in the last five years. In case of power outage, they have two back-up generators with enough fuel for one week. The tank is refilled when the fuel level reaches half-full.

We were provided a list of major equipment and instruments (**Exhibit 11**). Ms. Rangavajhula explained that the only equipment used in repackaging and relabeling commercial products for the U.S. market are three walk-in refrigerators – one for temporary storage during receiving operations, one for quarantine status materials, and one for released status materials.

[AD]

I reviewed the equipment qualification for the three walk-in refrigerators as described below. These were the only major equipment used in the repackaging and labeling of product manufactured for a US market. All three refrigerators are identical in dimension and function.

- Walk-In Refrigerator (EE-0417) Qualification Protocol No. EEQP0071 – The original equipment performance qualification was performed September 23, 2011. The equipment is requalified every three years with the last requalification performed January 23, 2018. This equipment is used for temporary storage only. The performance qualification included recording temperatures, every 15 minutes, from 14 thermocouples placed throughout the refrigerator and 1 control thermocouple placed at ambient temperature. The refrigerator was assessed with no load, full load (using foam blocks), an

open-door study (door is opened for 3 min, with load, temperature is monitored until stabilization), and a power failure (temperature is recorded after power is shut off until >7°C). Requalification omitted the no load testing and included the addition of 2 thermocouples placed directly underneath the fan units. All thermocouples were within 4°C at specific timepoints under all conditions assessed. No warm/cold spots were consistently identified and the placement of the permanent probe, in the middle of the refrigerator, is appropriate.

- Walk-In Refrigerator (EE-0386) Qualification Protocol No. EEQP0065 – The original equipment performance qualification was performed May 3, 2010. The equipment is requalified every three years with the last requalification performed August 7, 2019. The equipment is used for released storage. The performance qualification and requalification use the same procedures as described for EE-0417. Requalification omitted the no load testing and included the addition of 2 thermocouples placed directly underneath the fan units. All thermocouples were within 4°C at specific timepoints under all conditions assessed. No warm/cold spots were consistently identified and the placement of the permanent probe, in the middle of the refrigerator, is appropriate.

- Walk-In Refrigerator (EE-0087) Qualification Protocol No. 00EMI-V02 – The refrigerator is used for quarantine storage. The refrigerator was moved to the current facility in 2002. A temperature mapping of the refrigerator, with no load, was performed on July 18, 2002. A qualification system was put into placed in 2009 and a full qualification was performed on the equipment on January 5, 2010. The no load assessment was omitted as the refrigerator was already being used for storage. The equipment has been requalified every 3 after 2010 per the requalification described for EE-0417 with the last qualification performed June 19, 2019. No warm/cold spots were consistently identified and the placement of the permanent probe, in the middle of the refrigerator, is appropriate.

The following deviations were observed for the equipment:

- EE-0417 – During the last year, two deviations were recorded (-230.5°C dated 9/27/2018 and 20.9°C dated 1/30/2019, and 1.3°C, dated 10/25/2018). The first was recorded during calibration of the temperature probe and the calibration record was reviewed. The second was due to a change in the data acquisition system as an erroneous reading due to the transient conditions caused while transferring/connecting probes. This deviation was recorded for all three refrigerators. The third was recorded during the working day and was noted on the environmental monitoring report as being due to “supplies being loaded”. No further information was needed.

- EE-0386 – During the last year, two excursions were recorded. A deviation report was created for both excursions (initiated 1/30/2019 and 7/15/2019 respectively). The first was due to the change in the data acquisition system described above. The second was a dip in temperature to ~1.3°C on July 14, 2019 for ~1.5 hours (3 recorded excursions). The firm noted that one of the two compressors was failing to cut-off. The compressor was turned off, the door was opened for a brief period of time and within 20 min the temperature was back within range. The functional compressor continued, and temperatures were maintained with the acceptable range. The next day the solenoid and liquid line drier was replaced. The client [redacted] confirmed that the temperature excursion did not have a negative impact and all impacted products were acceptable.

- EE-0417 – During the last year, the only deviation was due to the change in the data acquisition system described above. In addition, one out of trend increase in temperature was observed ~every 24 hours during qualification. The temperature did not spike above 8°C. The firm suggested that the

spike was potentially due to a synchronization of the defrost cycle system. No further action was taken as the temperature was maintained in the 2 – 8°C specification range. A deviation was recorded on January 30, 2019 during calibration of the temperature probe and the calibration record was reviewed.

The SOP *DASYLAB® Data Acquisition System Operation Procedures* were reviewed for deviation procedures. Procedure VI.D. outlines that any excursion without a valid reason should be entered into the Deviation/Incident Report and shall be investigated. A discussion was had, and the firm proposed to add language outlining a "valid reason". No further action is needed.

PACKAGING AND LABELING SYSTEM

[SGD]

Management explained that the firm receives un-labeled drug products and packaging components, performs secondary packaging and labeling, and ships labeled drug product. The firm prints or embosses the respective lot number and expiry. The [redacted] is responsible for releasing all packaging components, and both unlabeled and labeled drug products. Additionally, the client is responsible for vendor qualification, retention samples, stability, validation, logistics, amongst others.

We reviewed the following packaging batch records (BR) without observation:

- [redacted] – 5000 vials; 100% reconciliation yield
- [redacted] – 1928 vials; 100% reconciliation yield
- [redacted] – 858 vials; 100% reconciliation yield
- [redacted] – 3430 vials starting to 3428 vials finished; 99.94% reconciliation yield (refer to deviation 2017D0056)
- [redacted] – 5880 vials; 100% reconciliation yield
- [redacted] – 5880 vials; 100% reconciliation yield

The *Label Request Record* has a header with the product name, label stock, color, print type, and date printed labels are needed. A label draft copy is pasted onto the form. The quantity required for labeling operations and needed for sampling is documented. The client approves and then the quality department approves the form. Similarly, the *Label Request Record* is utilized to document a sample of the lot and expiry when these are embossed on a carton, as proof of the stencil mark, according to Mr. Devansahayam.

The reconciliation yield includes all components: unlabeled vials, vial labels, vial cartons, package inserts, core boxes and box labels. Any defective or wasted materials must be destroyed in the presence of a quality representative. The batch records contain a respective specimen of the vial label, vial carton, package insert, and box label.

MANUFACTURING CODES

[SGD]

Mr. Arun Kantareddy, Vice President, Operations, explained that the manufacturing code assignment method remains the same as the August 2015 inspection.

All documented operations are given a unique identifying code, including packaging and labeling batch records, deviation reports, customer complaints, outgoing shipments, and incoming receipts. Each is comprised of the four-digit year, a capital letter indicating the type of operation based on the code below, and

a four or five-digit unique sequential event generated by their IDMS. The firm combines all products (commercial and clinical) when sequentially numbering their packaging and labeling batch records.

B = Packaging and labeling batch record
C = Complaint
D = Deviation
R = Received (five-digit)
S = Shipped (five-digit)

For example,

- 2017C0008 represents the eighth customer complaint received in 2017
- 2018B0097 represents the 97th packaging and labeling batch record created in 2018

COMPLAINTS

[SGD]

I reviewed SOP 2011.07, entitled *Customer Complaint Processing Procedure*, approved 11/25/15. Per the procedure, upon receipt of a complaint, a report is generated in IDMS and the system generates a unique nine-character identifier represented by the four-digit year, a "C," and a sequentially assigned four-digit number restarting at 0001 each year. The manager performs the complaint investigation and initiates corrective actions, recorded in the description section of the complaint report within IDMS. QA/QC reviews and approves the complaint within 10 business days unless delayed by the client. The report is provided to the respective client and the client's disposition of the report is recorded on the report.

According to Ms. Vijaya Rangavajhula, Vice President, Quality Assurance, the firm has received three customer complaints since the August 2015 inspection for U.S. commercial products. Two of them were deemed client responsibility because they were shipped to the [redacted] without noting issues, and the third was regarding an error in the batch record date of one lot. We reviewed the following customer complaints without observation:

- Complaint 2016C0006, initiated 06/07/2016, regarding batch record 2015B0171 in which the start date was entered incorrectly in IDMS. While closing the batch record in IDMS, the start date was not updated to 05/29/2015; instead the “batch created” date 05/28/2015 was checked inadvertently. This mistake was also not noticed by the quality department while reviewing and releasing the batch record. The client noticed this error while reviewing the APQR report and notified the firm. The root cause was identified as personnel negligence. They immediately corrected the start date in IDMS to 05/29/2015 and forwarded a revised APQR to the client. We observed in IDMS that the record was modified on 06/07/2016. The complaint file was completed on 06/20/2016 and approved on 06/28/2016.

- Complaint 2016C0012, initiated 09/08/2016, regarding a patient report that one vial of lot 2016B0236 was broken in the box upon delivery which was received from [redacted]. The firm verified that the batch record did not contain any issues during packaging and labeling operations. Also, shipping documents and confirmations from [redacted] were verified. The client initiated a product complaint themselves to investigate internally. No further information was provided regarding the investigation and most probable root cause determination. The firm assigned the root cause as client responsibility. The complaint file was approved on 11/16/2016.

- Complaint 2017C0008, initiated 09/11/2017, regarding a pharmacy observing two out of three vials of lot 17B0160 were broken upon receipt. The lot was shipped from the firm to the [redacted] without noting any issues during packaging and labeling, and no rejected or cracked vials found during internal inspection. The lot was not shipped from the firm to the pharmacy, but rather had an intermediate customer. The root cause was assigned as client responsibility. There was no action taken by the firm. The complaint file was completed and approved on 09/12/ 2017.

RECALL PROCEDURES

[SGD]

According to Mr. Arun Kantareddy, Vice President, Operations, on February 5, 2020, the firm has not performed any recalls for commercial products.

I reviewed SOP 6013.08, entitled *Drug Product Recalls*, approved September 5, 2019. The procedure states that commercial products are recalled following client specific requirements or procedures. I observed that the procedure still reflects the language as presented and discussed in the 2010 establishment inspection report, directly quoted here:

> The SOP states under part V, "Procedure:", "When a client's product is noted to expire in three (3) months (or a designated time period provided by the client) the client will be notified. Pending approval from the client, EMINENT will then generate an Investigational Drug Recall Notice to be sent to all sites involved by either a mass mailing or fax." I asked Dr. Thadikonda if he would be applying this recall procedure to commercial products. He told me they would not recall commercial products when they were noted to expire in three months. He stated that this only applies to clinical trial drug products. The SOP for Commercial Operations states in the event of a product recall "[redacted] will manage any product recall and Eminent shall follow [redacted] and Eminent SOP# 6013 for quarantine, return, and reconciliation". I explained to Dr. Thadikonda that if the firm plans to use SOP# 6013 for commercial recalls it should be clear as to the proper procedure to be used in a commercial product recall as opposed to a clinical trial product recall. Dr. Thadikonda acknowledged the observation and stated he would have the recall SOP updated.

I discussed with management that this portion of the procedure had not been revised. Mr. Kantareddy explained that this portion is applicable to clinical trial drug products, not commercial; however, the SOP does not delineate a difference. Mr. Anbu Devansahayam, President, explained that they would provide a list to the client of products shipped and stated that they could include that in the procedure. Additionally, he stated that they may revise the procedure to delineate differences between handling of commercial versus clinical product recalls.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

[SGD]

A Form FDA 483, *Inspectional Observations*, was not issued.

REFUSALS

[SGD]

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

[SGD]

On February 6, 2020, Microbiologist Derr and I, Investigator Dissmeyer, held a closing meeting with the following firm management team:

- Mr. Krupakar Paul Thadikonda, Ph.D., Director of Board
- Mr. Anbu S. Devansahayam, MS, President
- Ms. Vijaya L. Rangavajhula, Vice President, Quality Assurance
- Mr. Arun Kantareddy, Vice President, Operations

I read the following statement to Mr. Thadikonda:

> "The conditions observed may, after further review by the agency, be considered to be violations of the Food, Drug, and Cosmetic Act or other statutes. Legal sanctions available to FDA may include seizure, injunction, civil money penalties, prosecution, an untitled letter, or warning letter. The conditions observed may be determined to be violations. The primary purpose of this discussion is to, again, call attention to objectionable practices or conditions which should be corrected."

The following item was discussed with management during the closing meeting:

1. **The responsibilities and procedures applicable to the quality control unit are not in writing. Furthermore, changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit.**

   Specifically, your change management procedures, SOP 2017.07 and SOP 2029.03, do not describe the drafting and review process for proposed changes in sufficient detail. Furthermore, changes to procedures are not drafted and reviewed in a documented process by all relevant departments prior to quality approval of the procedure. For example, the following procedures were revised without a documented review of the draft by the respective departments: SOPs 2004, 2007, and 6334.

   Additionally, there is no assessment of change controls to ensure all relevant factors that may affect quality are documented. For example, the change request for replacement of the roof and HVAC system, request 2017RQ0001, did not include an assessment of the impact on the HVAC preventive maintenance schedule. Also, the duration (one versus multiple seasons) of the warehouse temperature mapping qualification was not documented.

   We observed that the change management procedures, SOP 2017.07, entitled *Documentation Revision Control Procedures*, effective 30Oct2018 (**Exhibit 12**, pages 1-6), and SOP 2029.03, entitled *Change Control Procedures*, effective 05Jan2010 (**Exhibit 12**, pages 7-9), do not detail the process for reviewing proposed changes to procedures prior to implementation. The *Change Request* document, form 054C.04, effective 01Jan2006 (**Exhibit 12**, page 10), does not require the review and approval of affected departments. Ms. Rangavajhula explained that per SOP 2029.03, step E, the change request form does not apply to SOPs, and rather, per step C, SOP 2017 applies. However, SOP 2017.07 does not provide instructions for the review of proposed changes by respective department management. The referenced form, *Documentation Revision Control Record*, form 024C, is a list of procedure versions and effective dates; it is not a review form for proposed changes prior to implementation.

Mr. Devansahayam explained that when a procedure revision is drafted, it is emailed to an "Eminent Operations listserve." The group reviews the proposed changes; however, this process is not documented in the procedure. Furthermore, we observed that documentation of the reviews (such as the review emails) are not attached to the procedure changes for SOP change controls that we reviewed. For example, we observed the following procedure changes were made effective without a documented review by all affected departments:

- SOP 2004 from version 08 to 09 (**Exhibit 12**, pages 11-20) - Mr. Kantareddy explained that three groups are affected by this procedure, as they pertain to investigational, not commercial, drug products: "IDR" receipt for incoming shipments, quality assurance for release, and "CDM/Programmer" for label printing issues. Mr. Devansahayam explained that he could not tell from the documentation who drafted and reviewed the changes; rather he could provide who prepared and approved the final version, Mr. Sanagapati from quality assurance. Ms. Rangavajhula explained that the other departments did not approve the revision before quality approved it for publication and training.

- SOP 2007 from version 06 to 07 (**Exhibit 12**, pages 21-28) - Mr. Kantareddy explained that Mr. Sanagapati (quality) drafted the change based on the "prepared by" entry. Due to a personal emergency in which the quality head was out of the office on extended leave, Mr. Kantareddy (operations) was delegated to and signed for approval in place of quality assurance, not on behalf of operations. Management explained that the procedure could not await the quality head's return to be made effective. There is no documentation of review for operations.

- SOP 6334 from version 03 to 04 (**Exhibit 12**, pages 29-36) – An employee from "CDM" prepared the revisions. This procedure affects project managers which report into Mr. Kantareddy (operations). He explained that his review was not documented.

Similarly, we observed that there was no assessment of change request 2017RQ0001 (**Exhibit 12**, page 37), regarding the replacement of the roof and HVAC system, to ensure that all relevant factors that may affect quality were documented. The change control did not include an assessment of the impact on the HVAC preventive maintenance schedule, which was shifted for periodic maintenance from the installation date. Also, the expected duration of the warehouse temperature mapping qualification was not documented to specify one season versus all four, for example.

The change control was initiated on 06/13/2017 and approved for implementation on 06/22/2017. We observed that the temperature mapping study was approved on 12/8/2017. The change request was completed and closed on 05/21/2018. Ms. Rangavajhula explained that management verbally discussed that they should monitor the variations of different seasons (such as for humidity) so they kept the change request open. Thus, while the mapping report was approved in December 2017, the change request remained open until May 2018. However, the discussion to extend the monitoring of warehouse temperature excursions was not documented, and neither were reviews of temperatures following the December 2017 report through May 2018.

Mr. Thadikonda acknowledged that he understood the discussion item as explained and discussed. He stated that they will have an internal meeting and follow-up with corrective actions. He committed to reviewing the change control procedure again. He also explained that previously it was a "one man show" in which he reviewed all proposed changes; however, with his retirement, he

would like to ensure there is an adequate change control procedure in place. He stated that while there may not be a formal procedure, personnel from quality do look at proposed changes. Mr. Thadikonda committed to submitting a voluntary written response to the agency, addressed to the Office of Pharmaceutical Quality Operations, Division I Director Ms. Diana Amador-Toro at ORAPharm1_responses@fda.hhs.gov, within 15 business days.

Finally, I read the statement on the Form FDA 483, *Inspectional Observations*, that the discussion item was our observation and not a final determination by the agency. A Form FDA 483, *Inspectional Observations*, was not issued.

ADDITIONAL INFORMATION

[SGD]

There is no additional information to report.

SAMPLES COLLECTED

[SGD]

No samples were collected.

VOLUNTARY CORRECTIONS

[SGD]

The firm's previous inspection, conducted August 12 – 14, 2015, did not result in the issuance of a Form FDA 483, *Inspectional Observations*.

During the August 2015 inspection, one item was verbally discussed with management as follows from the establishment inspection report:

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."

   During the current inspection, Mr. Paul Thadikonda, Director of Board, provided us their voluntary response to the agency from the previous inspection verbal observation dated August 27, 2015 (**Exhibit 13**). The firm committed to revising the customer complaint and deviation/incident report procedures in order to include more thorough investigation procedures and detail CAPAs.

   I observed that SOP 2013, entitled *Corrective and Preventive Action*, was revised to include two client related categories for root cause (client responsibility and client override) and version 3 was made effective 11/27/2015. Since then, there have been two additional revisions to add the root cause category "communications error" with the client, and to correct typographical errors, with the latest revision, version 5, made effective 09/20/2018.

   Mr. Arun Kantareddy, Vice President, Operations, explained that they added an investigation field to the deviation form to thoroughly document the actions taken. I observed that form 055C, *Deviation/Incident Report*, was revised to version 5 effective 11/27/2015, to add the new

"Investigation" field and add "Root Cause" to the form (**Exhibit 14**). It was further revised to version 6, effective 12/02/2016, to change the "Approved By (QA/QC)" to "QA/QC Disposition By."

Mr. Thadikonda explained that they changed the format of the investigation log and included a new root cause category of "client responsibility." He also stated that they hold quarterly meetings to discuss deviations and complaints received during previous quarter and discuss how to prevent recurrence through CAPAs. An effectiveness check is confirmed by the lack of issue recurrence at the next CAPA meeting.

EXHIBITS COLLECTED

[SGD]

1 EX 1 Government Contracts - 1 page
2 EX 2 Bills of Lading - 13 pages
3 EX 3 [redacted] Memorandum - 1 page
4 EX 4 Products for U.S. Market - 4 pages
5 EX 5 Obsolete Master Batch Records - 2 pages
6 EX 6 Organization Chart - 1 page
7 EX 7 SOP Index - 9 pages
8 EX 8 Deviation Log - 4 pages
9 EX 9 Procedure Flowcharts - 10 pages
10 EX 10 Facility Diagram - 1 page
11 EX 11 List of Major Equipment and Instruments - 4 pages
12 EX 12 Change Control Procedures and Examples - 37 pages
13 EX 13 August 2015 Inspection Response - 1 page
14 EX 14 Revision of Form 055C - 1 page

ATTACHMENTS

[SGD]

1 ATT Form FDA 482 - 3 pages

X Sena G. Dissmeyer -S
Digitally signed by Sena G. Dissmeyer -S
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Sena G. Z. Dissmeyer, Investigator
OPQO/Division 1
BLT-DO

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