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August 17, 2015

Food and Drug Administration  
Attn: Ms. Evelyn Bonnin, District Director  
600 Metro Drive, Suite 101  
Baltimore, Maryland 21215

**RE: Sentara Enterprises, dba, Sentara Home Infusion Pharmacy Service.  
Response to FDA Form 483 Issued 07/23/2015, Inspection Date Initiated 07/13/2015,  
FEI No. 3011627411 - Nebil A. Oumer, Investigator**

On behalf of Sentara Enterprises, dba Sentara Home Infusion Pharmacy Services, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information as described below on FDA's web site. I understand that the information that is disclosed may contain confidential commercial or financial information of trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 (0), and 5 U.S.C. § 552 (b) (4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing of the information with the public.

I have also attached for FDA review to be included in response support from Sentara Home Infusion Pharmacy Services as indication of our due diligence in addressing the bacterial findings prompting FDA investigation a letter from (b) (6)

Please add this letter to our FDA Form 483 response file.

Information to be disclosed: Sentara Enterprise, Inc., dba Sentara Home Infusion Pharmacy Services letter dated 08/12/2015 excluding attachments /exhibits provided, which responds to FDA's Form 483 dated 7/23/2015. In addition please exclude and hold confidential letter attached from (b) (6) regarding

investigation of bacterial infection reported to Sentara Health System in regards to FDA investigation for determining source of *leconostoc mesenterioides / lactis* infections.

Authorization is given FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Sentara Home Infusion Pharmacy Services and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

A handwritten signature in black ink, appearing to read 'James R Schwamburger'.

James R Schwamburger, RPh, MBA  
Director of Pharmacy  
Sentara Home Infusion Pharmacy Services  
535 Independence Parkway, Suite 300  
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August 12, 2015

Ms. Evelyn Bonnin, District Director  
Food and Drug Administration  
600 Metro Drive, Suite 101  
Baltimore, Maryland 21213

**RE: Sentara Enterprises, dba, Sentara Home Infusion Pharmacy Service.  
Response to FDA Form 483 Issued 07/23/2015, Inspection Date Initiated 07/13/2015,  
FEI No. 3011627411 - Nebil A. Oumer, Investigator**

### **Introduction**

Sentara Enterprises, Inc. provides Home Care Services and Medical Transport Services throughout the state of Virginia in numerous locations and into adjacent service area of North Carolina in the Outerbanks and Elizabeth City areas. Sentara Enterprises is a division of Sentara Health Care system which includes fourteen hospitals, over 27,000 plus employees and medical groups with over 700 physicians and Advance Practice Clinicians along with Optima Health a 450,000 plus beneficiary medical benefit plan. Sentara Enterprise Home Care Services includes Home Health, Hospice, Durable Medical Equipment Services and Home Infusion Pharmacy Services.

Sentara Home Infusion Pharmacy Services is duly licensed by State of Virginia operating under retail pharmacy class of trade per Virginia Board of Pharmacy law as a 503A pharmacy. Sentara Home Infusion Pharmacy has been providing service throughout the Sentara Health System network of communities served since 1989. Sentara Home Infusion Pharmacy was one of the first home infusion organizations to adopt and build a state of the art clean room in 2008 per required USP 797 regulations requiring a dedicated ISO7 clean positive pressure drug compounding area with ISO 5 Biological Cabinets. Sentara has and maintains a strong clinical and safety record with no issues concerning assurances of sterility and safety. Most importantly all Sentara Health Care System Pharmacies adhere to rigorous safety and quality standards for its compounded preparations. Sentara Home Infusion Pharmacy Services only fills prescriptions for individually identified patients pursuant to a valid prescription from a prescriber licensed in the states we service areas and as required by Section 503A of the Federal Food, Drug and Cosmetic Act (FDCA). Sentara Home Infusion Pharmacy does not engage in any office use compounding, or compounding in anticipation of receiving prescriptions from prescribers, it only compounds preparations for specific patients. Sentara Home Infusion Pharmacy did compound "high-risk" sterile preparations for specific pain management patient prescriptions which was less than 3% of our compounding medications. Sentara Home Infusion Pharmacy Services has stopped and will no longer produce "high-risk" (non-sterile to sterile) compounds effective August 11, 2015. Sentara Home Infusion Pharmacy Service operates under Section 503A of FDCA thus adhering to the USP CHAPTER <797> standards for pharmacy compounding practices and is exempt from cGMP.

Sentara feels strongly that the observations in the FDA 483 to be reviewed in this response are supportive to improve our operations and clinical standards of practice care and will be utilized to review, re-educate staff, and improve our operational policies and procedures to assure USP CHAPTER <797> standards are met and exceeded at all times.

Please note Sentara Home Infusion Pharmacy Services has been responsive to FDA and supportive of information requested since first contacted by FDA Representative Russell Fortney RPh, on Friday after business hours June 12, 2015. Director of Pharmacy contacted Mr. Fortney back on Monday, June 15, 2015 and discussed the situation with regards to two pediatric TPN patients on our Home Infusion Services from Children's of Kings Daughter's Hospital (CHKD). Pharmacist Laura Borowski, Pharm D with Sentara Home Infusion Pharmacy was contacted on June 15<sup>th</sup> as well by Norfolk Health department identifying two pediatric patient cases with infection of bacteria –

*Leuconostoc*. However, both cases identified two separate strains one with *Leuconostoc-mesenteroides* and the other *Leuconostoc-lactis*. Laura Borowski, PharmD, immediately notified her Pharmacy manager, Dontel Morris, Pharm D and myself and began pulling clinical compounding records and supplies for review by Health Department agent. A STARS (Sentara Tracking and Reporting System) incident was filed on both cases and updated as information was identified with various sources reporting.

Russell Fortney, FDA worked with Sentara to obtain patient compound records for these two patients as well as identifying all drug and supply lot numbers utilized for each compounded nutrition support product. Mr. Fortney identified in review of other cases of this bacteria reported in recent months that two drug product lot numbers were found to be common to each case.

**Products Identified:**

- Baxter Dextrose 70% NDC # 00338-0719-06, Lot # C963041
- Sandoz Pediatric MVI NCE # 54643-5846-1, Lot # EM7833

On June 25, 2015 Sentara Home Infusion Pharmacy Services worked with Sentara Pharmacy System Vice President, Tim Jennings issued a SBAR (attached) to all pharmacies in Sentara network to review inventory and quarantine these two products specific lot numbers. Sentara Home Infusion Pharmacy quarantined the remaining stock of both products lot numbers and these products were provided to the FDA investigators on July 22, 2015 for further FDA analysis.

As noted Sentara Home Infusion Pharmacy Services and our Sentara Health Care Pharmacy System has worked to support the FDA in the endeavors to uncover the source and cause of these two TPN pediatric patient bacterial infections. To date the review has not determined the source of this infection as originating in compounded products, within the compounding facility process nor has a link amongst all the cases found for this bacterial infection to our knowledge be linked to a particular product or matched as a specific source for the infectious bacterial- *lueconostoc*.

Please accept the following responses to the observations made by Investigators, Nebil Oumer and Wilfred Darang who visited our site on July 13 to July 23, 2015 as reported in FDA 483. Please note both gentleman were extremely professional, insightful and supportive of the operations need to continue operate patient compounding while performing their investigations.

**RESPONSES TO INSPECTOR OBSERVATIONS IN ORDER PRESENTED**

**FDA OBSERVATION # 1**

Procedure designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

**FDA INSPECTOR OBSERVATIONS**

On 07/13/15, the following aseptic techniques were observed in cleanroom in cleanroom:

- A.) An operator was observed placing tube tips (used for puncturing vials and bags containing sterile material) on the bench top inside a Biological Safety Cabinet (BSC) before it was disinfected during a set-up for sterile drug production
- B.) A gowned operator was observed leaving the BSC/ hood in the middle of an operation (filling of sterile drug product into elastomeric infusion devices) to grab supplies from the gowning area (outside the cleanroom). When she returned she continued with the operation without disinfecting her gloves. There is no procedure in place that prevents operators from exiting the cleanroom area to grab supplies from non-classified areas (gowning room and hall way) fully gowned.

- C.) An operator was observed placing a syringe (used for transferring diluents or drugs from vials to multiple elastomeric infusion device or aka home-pump) on the bench top inside the BSC; the syringe is not disinfected in between filling or transferring diluents or drugs into other elastomeric infusion devices.
- D.) Multiple operators were observed introducing material (i.e. diluents or components) to be used for sterile drug manufacturing, into the BSC/hood without disinfecting the outside cover.
- A.) All pharmacy IV personnel staff were verbally reminded and educated on July 24<sup>th</sup> staff meeting to follow and adhere to departmental and USP Chapter <797> policies and procedures at all times in regards to cleaning entire area inside the Biological Safety Cabinet with appropriate cleaning disinfectants prior to compounding sterile products. All pharmacy IV personnel staff was assigned to complete Fundamentals of Sterile compounding training modules in Critical Point Simplifi eLearning by October 31<sup>st</sup> in order to reinforce and maintain sterile compounding procedures when mixing CSPs.**
- B.) All pharmacy IV personnel staff were verbally reminded and educated on July 24<sup>th</sup> staff meeting to follow and adhere to departmental and USP Chapter <797> policies and procedures at all times in regards to disinfecting sterile gloves with an appropriate cleaning product (IPA 70%) when exiting and returning BSC workstation. The supplies in question are vital to daily pharmacy compounding operations are located in designated anteroom areas and are not beyond the line of demarcation located in the cleanroom area. All pharmacy IV personnel staff were assigned to complete Fundamentals of Sterile compounding training modules in Critical Point Simplifi eLearning by October 31<sup>st</sup> in order to reinforce and maintain sterile compounding procedures when mixing CSPs**
- C.) All pharmacy IV personnel staff were verbally reminded and educated on July 24<sup>th</sup> staff meeting to follow and adhere to departmental and USP Chapter <797> policies and procedures at all times in regards to disinfecting all transfer devices (syringes, vented needles, transfer pins, etc.) with an appropriate cleaning product (IPA 70% spray or wipes) prior to use when compounding sterile products. All pharmacy IV personnel staff were assigned to complete Fundamentals of Sterile compounding training modules in Critical Point Simplifi eLearning by October 31<sup>st</sup> in order to reinforce and maintain sterile compounding procedures when mixing CSPs**
- D.) All pharmacy IV personnel staff were verbally reminded and educated on July 24<sup>th</sup> staff meeting to follow and adhere to departmental and USP Chapter <797> policies and procedures at all times in regards to disinfecting all materials used for sterile compounding prior to placing items inside BSC for manufacturing with an appropriate cleaning product (IPA 70% spray or wipes) prior to use when compounding sterile products. All pharmacy IV personnel staff were assigned to complete Fundamentals of Sterile compounding training modules in Critical Point Simplifi eLearning by October 31<sup>st</sup> in order to reinforce and maintain sterile compounding procedures when mixing CSPs**

#### **FDA OBSERVATION # 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

#### **FDA INSPECTOR OBSERVATIONS**

- A.) Sterile drug products produced from non-sterile components are sterile filtered through a 0.2 micron filter. However, the firm does not perform any filter integrity testing after producing drug products purported to be sterile. Currently, products such as Hydromorphone, Morphine, Fentanyl, Bupivacaine and Clonidine are sterile filtered for intrathecal administration.
- B.) Currently media-fills are conducted to monitor operators' aseptic technique. However, no media fill study was conducted to simulate the production of sterile drug products produced from non-sterile components. Examples of these sterile drug products include Hydromorphone, Morphine, Fentanyl, Bupivacaine and Clonidine.

**A.) Effective August 11<sup>th</sup>, Sentara Home Infusion Pharmacy department will cease compounding sterile products from non-sterile products.**

**B.) Current media-fill testing monitors low and mid-risk aseptic technique. Effective August 11, 2015 - Sentara Home Infusion Pharmacy department will cease compounding high-risk sterile products, thus alleviating the need to test pharmacy personnel for high-risk aseptic technique.**

#### **FDA OBSERVATION # 3**

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

#### **FDA INSPECTOR OBSERVATIONS**

During the inspection of your firm, the operators we observed performing aseptic operations in the ISO 5 hoods were wearing non-sterile gowns. Specifically, the laboratory coat, face mask and pants are not sterile. Additionally, the face mask does not fully cover operator's face.

**Pharmacy department follows current IV Room Personal Protective Equipment Garbing policy and procedure that which states use of non-shedding gowns. USP Chapter <797> does not specify a required gown type (sterile, non-sterile, etc.); facemask type (fully face cover or partial). Sterile gloves are required per USP Chapter <797>.**

**Sentara Home Infusion Pharmacy is a 503A retail class of trade, licensed and inspected per the laws of the Virginia Board of Pharmacy which requires pharmacy to operate and practice under the guidelines established in the USP Chapter <797> standards.**

#### **FDA OBSERVATION # 4**

##### **Facilities and Equipment**

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

#### **FDA INSPECTOR OBSERVATIONS**

Biological Safety Cabinets (BSC)/Hoods #2 & #4, which are ISO 5s, are located in a clean room classified as ISO 7. BSC #2 is used for Total Parenteral Nutrition (TPN) bag production only and BSC #4 is used for producing products

such as, Meropenem (10 ml syringe) and large volume parenterals such as Vancomycin HCl and Daptomycin. The following deficiencies were observed in the above listed BSCs/Hoods: in the above listed BSCs/Hoods:

A.) Stained ceiling near the entrance of the gowning area to the clean room. Various types of materials such as vitamins and sterile water are kept under the ceiling.

B.) Rusted vents were observed on Hood #2 (used for preparing TPNs).

C.) Rust was observed in the HEPA filter grills inside Hood #2.

D.) A black substance was observed above the HEPA filter grills (Hood #2).

E.) Minor rusting was observed on the HEPA grills inside Hood #4.

F.) Rust and foreign black substance was observed above the HEPA filters inside Hood #4.

G.) Stains on the inside of roof and exposed light bulb were observed inside Hood #4

H.) Rust and chipped paint was observed on the vents of Hood #4.

**A.) Stained ceiling tiles near the entrance of the gown area to the clean room have been replaced by new ceiling tiles.**

**B.) Biological Safety Cabinet #2 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**C.) Biological Safety Cabinet #2 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**D.) Biological Safety Cabinet #2 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**E.) Biological Safety Cabinet #4 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**F.) Biological Safety Cabinet #4 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**G.) Biological Safety Cabinet #4 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

**H.) Biological Safety Cabinet #4 is scheduled to be removed and replaced with a new Iso-5 vertical HEPA unit the weekend of October 24<sup>th</sup>-25<sup>th</sup>.**

#### **FDA OBSERVATION # 5**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

#### **FDA INSPECTOR OBSERVATIONS**

A.) Personnel monitoring is conducted on a monthly basis, whereby only the finger-tips of the operators are monitored. Environmental sampling is conducted for bench tops (BSCs), counters, and sinks on a monthly basis. The sampling medium (paddle) used for finger-tips and surface sampling is currently not tested for growth promotion. The "Paddle" is also used for air sampling (passive) in the BSC on a monthly basis.

B.) No settle plates, active air and non-viable air is monitored in the BSC during aseptic operations.

**A.) The EnviroTest media paddles are tested for growth promotion on bench tops, counters, and sinks for surface sampling via incubation at 30-35 C for 48 to 72 hours within the pharmacy.**

**Effective August 2015, if growth promotion is found, the sample will be overnight shipped to Dynalabs or any future contracted quality lab service to identify the growth on the paddles / media. All data results will be maintained and analyzed for trends as to locations and be incorporated into cleaning maintenance plans.**

**B.) Pharmacy utilizes EnviroTest media paddles instead of settle plates. Pharmacy will implement a policy to perform active air and non-viable air inside the BSC during aseptic operation**

#### **FDA OBSERVATION # 6**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

## FDA INSPECTOR OBSERVATIONS

A.) The following disinfectants are used for sanitizing the BSCs and the surrounding areas: 70% IPA, "Peridox RTU" (label claims it's fungicidal, sporicidal and virucidal), "Accel TB" (label claims it's bactericidal & virucidal), and pre-soaked wipes "Prostat Sterile." No efficacy study was performed to determine if these disinfectants are capable of reducing the microbial load to an acceptable level in the BSCs and other surfaces (i.e. bench tops, walls and floor) in the cleanroom (ISO 7) where aseptic operations take place.

B.) Cleaning procedure, P-304.2 entitled "CLEANING AND DISINFECTING OF THE COMPOUNDING AREA" does not clearly indicate the type of disinfectants to be used. Specifically, there is no mention of the various disinfecting agents used in the ISO 5 (BSC/Hood) area currently. Additionally, 70% IPA and the sporicidal disinfectant ("Peridox RTU") are not being used in the cleanroom or the Hoods in an alternating fashion.

**A.) Pharmacy is a 503A and follows USP Chapter <797> guidelines which does not require efficacy studies be performed on disinfectants utilized in cleanroom maintenance. Pharmacy will continue to perform per policy and procedures routine environmental sampling for air, surface and glove finger-tips. Sampling results will be used to track and evaluate the effectiveness of the disinfectant products used in clean room maintenance. Based on results of CFU counts identified Pharmacy will take appropriate actions from this routine data to trend and evaluate the disinfectants utilized to assure effectiveness as required in USP Chapter <797> and VABOP law.**

**B.) Pharmacy added the name of the products used in the clean room to our policy and procedure (see attached Buffer/Cleanroom maintenance Policy) and will use disinfectant products in an alternating fashion effective immediately per policy guidelines established. Sentara Home Infusion Pharmacy is a 503A retail class of trade, licensed and inspected per the laws of the Virginia Board of Pharmacy which requires pharmacy to operate and practice under the guidelines established in the USP Chapter <797> standards.**

## FDA OBSERVATION # 7

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

## FDA INSPECTOR OBSERVATIONS

The last qualification of the Biological Safety Cabinets/ISO 5 Hood was conducted in June 2015 and it did not challenge all of the BSCs during the smoke study under dynamic conditions.

**Per review of final report by Biologic Control Service, it was determined that the BSCs in our IV clean room were tested under dynamic conditions. Further questioning of Biological Control Services operator by FDA inspector noted operated tested in dynamic conditions but not to full extend expected by inspector due to full staff in clean room operations were not present at time.**

**All future testing with outside testing operators will be scheduled at time of peak dept. operations to assure full dynamic testing interpretation and functional operations meet this compliance requirement.**

**A full Cleanroom testing and evaluation will be performed by Biological Control Services on October 26, 2015 to approve ISO7 and ISO 5 areas post removal of older Biological Safety cabinets and renovations of cleanroom with new ISO-5 areas to be installed by Travis Clean Air.**

## FDA OBSERVATION # 8

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

## **FDA INSPECTOR OBSERVATIONS**

No sterility and endotoxin testing has been conducted for sterile drug products produced from non-sterile components since November, 2014. Additionally, TPNs are tested for sterility on a weekly basis and other sterile drug products are tested periodically (up to every 6 months) for sterility. The sterility samples (on a TSB Medium) for the TPNs were incubated at a temperature ranging from 33<sup>o</sup>-35<sup>o</sup>C for 14 days. However, the direction for the sampling unit, Quick Test System, instructs the user to incubate at 20<sup>o</sup> to 25<sup>o</sup>C. Furthermore, the fir did not evaluate the sterility samples using media intended to support anaerobic microbes

**Effective August 11, 2015, Sentara Home Infusion Pharmacy department will cease compounding sterile products from non-sterile products ("high-risk").**

**Sentara Home Infusion Pharmacy is a 503A retail class of trade, licensed and inspected per the laws of the Virginia Board of Pharmacy which requires pharmacy to operate and practice under the guidelines established in the USP Chapter <797> standards. All requirements for sterility testing are followed per USP Chapter <797> and the Virginia Board of Pharmacy requirements.**

### **FDA OBSERVATION # 9**

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

## **FDA INSPECTOR OBSERVATIONS**

No stability or potency testing has been conducted for sterile drug products produced from non-sterile components since November 2014. Examples of non-sterile powders include Hydromorphone, Morphine, Fentanyl, Bupivacaine and Clonidine

**In the absence of sterility testing, all non-sterile (high-risk) drug products have a BUD (Beyond Use Date) of 24 hours.**

**Effective August 11<sup>th</sup>, Sentara Home Infusion Pharmacy department will cease compounding sterile products from non-sterile products.**

**Sentara Home Infusion Pharmacy is a 503A retail class of trade, licensed and inspected per the laws of the Virginia Board of Pharmacy which requires pharmacy to operate and practice under the guidelines established in the USP Chapter <797> standards.**

### **FDA OBSERVATION # 10**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

## **FDA INSPECTOR OBSERVATIONS**

The environmental monitoring records from 05/01/14 to 05/30/15 contain positive results that were obtained for personnel's finger-tips. No investigation was conducted to determine the source of the contamination and impact on product quality and safety. Furthermore, the microbes were not quantified and identified, and no alert or action limit is established for environmental monitoring. The observed growth was for the following "finger-tip-testing".

- Testing date: 05/09/14: Left hand
- Testing date: 05/16/14: Left hand
- Testing date: 05/27/14: Left hand and second operator had growth on his right-hand
- Testing date: 05/30/14: Left hand
- Testing date: 11/26/14: Left hand
- Testing date: 05/28/15: Left hand

Additionally, no trending is performed for monitoring environmental conditions.

**Per established department guidelines for fingertip testing effective October 1, 2015, any failed 1<sup>st</sup> attempts are immediately retested due to possible improper manipulation of testing paddles. A 2<sup>nd</sup> failed test will result in that sample being analyzed for growth promotion and that pharmacy staff member will not be allowed to perform compounding CSPs until their admixture technique is reviewed by management and brought up to USP Chapter <797> standards**

#### **FDA OBSERVATION # 11**

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

#### **FDA INSPECTION OBSERVATIONS**

There are no calibration and qualification records for incubator, Boekal Industries, Model 133000. This incubator is used for incubating environmental samples from the cleanroom and ISO 5 Hoods, and for TPN Sterility samples.

**Pharmacy will obtain NIST calibrated thermometer and contract services for annual (or per manufacturer recommendations) Incubator Calibration validation. The NIST thermometer will be utilized to monitor and check all Drug and Cleanroom storage devices monthly and recorded in Simplify797 software. Annual calibration by outside testing firm will be maintained and documented annually in tracking software.**

#### **Conclusion**

Sentara Home Infusion Pharmacy Services is a 503A retail Pharmacy operating in good standing with Virginia Board of Pharmacy and adheres to USP Chapter <797> operating standards for compounding individual patient prescription medications. Sentara was inspected by VABOP in coordination visit with the FDA investigators on July 13-15, 2015. All VABOP inspection findings were corrected and/or noted date of facility improvement plan schedules. VABOP fines were submitted along with the VABOP recommendation corrections on August 6, 2015. In addition the VABOP has been notified and Pharmacy Renovation fees submitted for scheduled Cleanroom improvement plans. VABOP has scheduled to be present on October 27, 2015 to review and approve renovations. Pharmacy cleanroom equipment (4 ISO-5 BSC's) in positive pressure ISO-7 clean room area is scheduled to be replaced on October 24 – 26, 2015 by cleanroom contractor, Travis Air. A NuAire BSC-A-2 for Hazardous (Chemo-hood) compounds will be installed at same time replacing the older identified chemo-hood in our negative pressure (USP 800) area.

All Pharmacy Staff was in-serviced and re-educated to the findings of FDA 483 Observations on July 24, 2015 and further mandatory clean room maintenance and operational education requirements were assigned to be completed by October 1, 2015.

All clean room policies and procedures were reviewed and updated to match Hospital Pharmacy System approved Policies and procedures for clean room compounding following USP-797 guidelines for low and medium risk compounding standards of operations. These policies will be reviewed with all Staff meeting on August 12<sup>th</sup> and implemented into Simplify797 software compliance tracking program for all staff access by August 30, 2015.

**(Copies of Updated Policies Attached for Review)**

All "high-risk", (non-sterile to sterile) injectable compounds has ceased as of August 11, 2015 thus the Pharmacy will only operate and provide compounds meeting USP-797 low to medium risk category. All Beyond Use Dates (BUD) will follow the USP-797 guideline standards. USP-797 establishes the BUD for the sterility of compounded preparations in the subsections for low, medium, and high-risk products. There is no requirement for sterility testing of low or medium-risk compounded preparations when the BUD assigned the sterile preparation is within the allowable limits set forth in USP-797. Sentara Home Infusion Pharmacy Services sterile compounded preparations do not exceed the allowed sterility dating for low, medium or high-risk compounded sterile preparations. Sentara Home Infusion Pharmacy Services as noted above will no longer perform high-risk compounding effective August 11, 2015.

Sentara Home Infusion Pharmacy Services respectfully submits the response to FDA 483 Observations and requests a prompt response to our operational action plans noted as well as conclusion of all sample investigation results. Please contact Director of Pharmacy or Pharmacist in Charge for further information requests. Respectfully submitted,

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James R Schwamburger  
Director of Pharmacy  
Sentara Home Infusion Pharmacy Services

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E. Dontel Morris, PharmD  
VABOP Pharmacist in Charge