DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	3/21-3/24/16 & 4/11/16
	FEI NUMBER 3011116100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Andreas D. Dettlaff, Owner

FIRM NAME	STREET ADDRESS
Absolute Pharmacy, LLC	16011 N. Nebraska Avenue, Suite 103
CITY, STATE AND ZIP CODE Lutz, FL 33549	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

Specifically,
A. The media fills performed to qualify pharmacists in aseptic operations of sterile drug products were not adequate in that it did not closely simulate current processes and the most challenging or stressful conditions encountered during preparation of drug products as per SOP No.7.007.3 Media Fill for High Risk Compounding. Upon review of media fill documentation the following deficiencies were found:

a) None of the "qualified" aseptic pharmacists had adequate documentation of at least one (1) media fill that simulates current processes and represents worst-case conditions, i.e. (b) (4) (b) (4) (b) (4), which includes: gowning/re-gowning, fatigue, etc. that would provide a challenge to aseptic operations. There was also no documentation that media fills are observed by a qualified person to assess aseptic technique and behavior.

b) The documentation for the media fill performed by aseptic pharmacist R.R. on (b) (4) was not representative of current practices. The media fill had no documentation that fingertips were sampled for microbiological contamination, no documentation of environmental monitoring (gown, air, and surface), and the time duration of the media fill was not documented. There was no documentation that the (b) (4) (b) (4) were incubated and inspected for microbial growth. The aseptic pharmacist/Pharmacist in Charge, R.R stated that during the media fill his gloves were tearing exposing his skin. This incident was not documented on the media fill. There was no documentation that the pharmacist passed his media fill, but he has been conducting sterile operations for the past 4 months.

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	Jessica L. Pressley	Jessica L. Pressley, Drug Investigator	04/11/2016

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c) The documentation for the media fill performed by aseptic pharmacist (b)(7)(C) (b)(6). on (b)(4) was not representative of current practices as he only produced (b)(4) when he is currently allowed to produce up to (b)(4) The media fill had no documentation that fingertips were sampled for microbiological contamination, no documentation of environmental monitoring (gown, air, and surface), and the time duration of the media fill was not documented. The media fill stated that (b)(4)) were (b)(4) therefore the (b)(4) Pharmacist in Charge, R.R.

d) The documentation for the media fill performed by aseptic pharmacist (b)(7)(C) (b)(6). on (b)(4) was not representative of current practices. The media fill had no documentation that fingertips were sampled for microbiological contamination, no documentation of environmental monitoring (gown, air, and surface), and the time duration of the media fill was not documented. The media fill stated that (b)(4)) (b)(4) therefore the (b)(4) (b)(4) Pharmacist in Charge, R.R.

e. Your firm lacked a disqualification and re-qualification program for aseptic pharmacists when sterility failures of batches or out-of-specification environmental sampling results are reported. For example, Testosterone Cypionate 210mg/mL multidose 5mL vials, lot # J1315MCPL produced by aseptic pharmacist (b)(7)(C), (b)(6) on 10/13/15 failed sterility testing. The previous media fill performed by this pharmacist on (b)(4) was inadequate as it was not representative of current practices. However, no action was taken by your firm to restrict this pharmacist from performing aseptic operations until a successful media fill is performed.

B. During a demonstration of gowning and sterile operations for Cyanocobalamin 1,100mcg/mL performed by aseptic pharmacist ((b)(6), (b)(7)(C) in the ISO 5 LAFW on 3/22/16, I observed the following deficiencies in aseptic technique:

a) Pharmacist entered the gowning room (ISO 7), removed non-sterile garments that were previously worn in the ISO 8 area, sanitized hands, opened the sterile face mask, fixed (b)(6) (b)(7)(C) hair net, touched hair/face, then opened the sterile gown and put it on touching the interior/exterior part of the gown, lastly put on the (b)(4) goggles with (b)(6), (b)(7)(C) bare hands.

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b) The (b) (4) conducted by the Pharmacist was inadequate as no (b) (4) was placed into the (b) (6), (b) (7)(C). Instead, the pharmacist stated that since sterile product remained in the (b) (4) connection (b) (6), (b) (7)(C) was able (b) (4) (b) (4) (b) (4)

c) The pharmacist was observed assembling the (b) (4) syringe (b) (4) to the IV bag containing sterile product to then fill the sterile product into the individual vials. The pharmacist jammed the plunger of the (b) (4) syringe causing the (b) (4) to dislodge allowing for sterile product to leak out onto the surface of the ISO 5 LAFW. The pharmacist continued to fill the vials but stated that these vials would be destroyed.

d) The pharmacist was observed working directly over the open vials (largest batch can consist of as many as (b) (4) vials).

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

a) Your firm's (b) (4)) has not been validated to include (b) (4) and (b) (4) .

b) Your firm's (b) (4) in the (b) (4) used to sterilize Testosterone products has not been validated. In addition, according to the manual, (b) (4) (b) (4) are intended to (b) (4)

c) Your firm's lyophilization (b) (4) performed in the (b) (4) (b) (4) used for Sermorelin, HCG, Methylcobalamin and IGF has not been validated. This includes lack of validation data for the (b) (4) and (b) (4)

*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

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

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*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

Specifically,
A. Upon observation of cleaning activities prior to sterile operations for Cyanocobalamin 1,100mcg/mL performed by aseptic pharmacist ((b)(7)(C), (b)(6)) I noted the following deficiencies:

a) Prior to working in the ISO 5 LAFW, the pharmacist only sanitized the surface of the hood and working bench within the ISO 5 buffer room with (b)(4) sterile (b)(4) wipes (b)(4) ((b)(6), (b)(7)(C)) failed to wipe down the ceiling, sides, and middle bar of the LAFW Hood where the IV bag is placed containing sterile product after (b)(4) as well as the chair that ((b)(6), (b)(7)(C)) sits in during filling operations within the ISO 5 buffer room. I observed a previously opened (b)(4) sterile (b)(4) wipes within the ISO 8 room that was being used to wipe off components. The pharmacist also stated that this practice occurs within the ISO 5 buffer room.

b) The pharmacist introduced a pump into the ISO 5 LAFW without first wiping down the pump and cord with sterile (b)(4).

B. Upon observation of environmental conditions during filling and at the completion of sterile operations for Cyanocobalamin 1,100mcg/mL performed by aseptic pharmacist ((b)(7)(C), (b)(6)) I noted the following deficiencies:

a) No viable air monitoring was conducted during filling operations.

b) Fingertip sampling was inadequate as the pharmacist was observed using (b)(4) and dabbing ((b)(6), (b)(7)(C)) fingertips on ((b)(6), (b)(7)(C)) right hand onto the plate then repeating the technique with ((b)(7)(C)) left hand covering the previously plated fingertip sample.

c) The pharmacist was observed swabbing the surface of the (b)(4) with a dry Sterile Rectangular Foam Swab with the technique of (b)(4) Using those (b)(4), and technique, the pharmacist used another swab to swab the (b)(4) and plated it. Your firm has not demonstrated that (b)(4) would recover organisms on the surfaces. In addition, if positive results are obtained your firm would not be able to identify the location of the positive sample.

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4. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. Specifically, the latest two (2) qualifications of the ISO 5 buffer room and the one ISO 5 hood completed on (b) (4) by a contractor do not document if qualifications were performed under static or dynamic conditions with maximum number of personnel. In addition, your Pharmacist in Charge stated that the smoke study performed in the (b) (4) was not conducted under dynamic conditions. Your firm failed to conduct a smoke study in the ISO 5 buffer room to illustrate the practice of (b) (4) from the ISO 5 Hood to the (b) (4)

*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

5. Any unexplained discrepancy or the failure of a batch and any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed.

Specifically,
A. Your firm failed to establish and follow an Out of Specification (OOS) Procedure. As a result, your firm failed to conduct investigations when an OOS results were received by your firm.

a) OOS for high potency 124.2% (spec. (b) (4) was received by your lab on 9/17/15 for B12 in the finished sterile product, MIC+B12 25/50/50+ 1mg/mL multidose 30mL vials, lot # I1415MCPL. Your firm released the lot of (b) (4) vials on 9/16/15 for distribution prior to receiving the potency results. No recall was conducted.

b) Your firm generated a Quality Related Event Report Form (no SOP in place regarding this form) on 1/6/16 for "26% low volume" for the Cyanocobalamin 1100mcg/mL multidose 10mL vials, lot # A0516TCPL. No investigation was conducted. There is no documentation within the batch record to show that this batch was reworked. (b) (4) vials were pending release. The visual inspection of this lot was not conducted and this lot was not reviewed and released by the Pharmacist in Charge. This lot was shipped to a patient on 1/29/16.

c) Your firm generated a Quality Related Event Report Form (no SOP in place regarding this form) on 10/13/15 for a sterility failure for Testosterone Cypionate 210mg/mL multidose 5mL vials, lot # J1315MCPL. No investigation was conducted by the firm or the control testing lab (CTL). No documentation was provided for the re-training of the pharmacist. This batch was rejected according to the batch record.

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d) Your firm generated a Quality Related Event Report Form (no SOP in place regarding this form) on 2/12/16 for an endotoxin failure for L-Carnitine 500mg/mL multidose 30mL vials, lot # B1216TMPL. No investigation was conducted by the firm or the control testing lab (CTL). No documentation was provided for the re-training of the pharmacist. This batch was rejected according to the batch record.

e) Your firm generated a Quality Related Event Report Form (no SOP in place regarding this form) on 3/10/16 for low potency for Methylcobalamin 10mg. No lot # was provided. No investigation was conducted by the firm. No documentation was provided for the re-training of the pharmacist. This batch was rejected according to the batch record.

6. Your firm failed to follow SOP No. 9.014 Procedures in the Event of Nonconformance (NC) of Preparations or Chemicals. As a result, your firm failed to conduct an investigation when an NC occurs as evidenced by the following:

a) During the visual inspection of Testosterone Enanthate 210mg/mL, Lot # A2916TMPL on 1/29/16 your pharmacist (b)(6), (b)(6) observed two vials containing particulate. Your firm released the lot on 2/9/16 of (b)(4) vials for distribution and it is unclear if the two vials containing the particulate were rejected. No recall was conducted. In addition, the batch record does not state that a (b)(4) was conducted on the (b)(4) used during (b)(4) sterilization.

b) During the current FDA inspection, I reviewed the batch record for L-Carnitine 100mg/mL multidose 30mL vials, lot # A2516MCPL. I observed that there was no documentation within the batch record for (b)(4) using an (b)(4). Also, non-viable air was not monitored before operations were conducted. This batch of approximately (b)(4) vials (# of vials released was not documented in the batch record) was reviewed and released by your Pharmacist in Charge on 2/1/16 based on the sterility test results of (b)(4) vials conducted by your control testing lab (CTL).

c) Your firm generated a Quality Related Event Report Form (no SOP in place regarding this form) on 1/26/16 for vials of Ascorbic Acid 500mg/mL bursting within the (b)(4) (ascorbic acid is (b)(4) sterilized). No lot # was provided. No documentation was provided for the re-training of the pharmacist.

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7. There are no written standards or specifications, methods of testing, methods of cleaning, methods of sterilization, and methods of processing to remove pyrogenic properties. Specifically,

a) The (b) (4) depyrogenation (b) (4) has not been adequately validated as the firm failed to specify the (b) (4) This process is used for all laboratory glassware (i.e. glass vials) used in the filling of sterile drug products.

b) The (b) (4) sterilization (b) (4) have not been adequately validated as the firm failed to specify the (b) (4) . This process is used for finished product vials, rubber stoppers and caps used in the filling of sterile drug products.

c) Glass vials and beakers that are depyrogenated in-house are not identified in a way that would allow a trace back to the depyrogenation (b) (4) /batch.

*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

8. For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements.

*Repeated Observations from the previous Form FDA-483 issued 11/19/14 and Warning Letter issued 4/27/15.

Specifically,
A. Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

a) Your firm has not validated sterility and endotoxin testing to ensure substances in your product formulations do not interfere with the test for the following products: MIC+B1+B12, Sermorelin and HCG 5,000IU/11,000IU. During the review of the method suitability for sterility testing for EDTA 150mg/mL it was discovered that the conclusion from your control testing lab (CTL) stated that your firm's drug product interferes with the (b) (4) Your firm did not receive or review the results to determine what corrective

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actions needed to be taken.

b) Your firm has never performed testing to determine the preservative (i.e., (b) (4) content for any of your liquid sterile drug products prior to distribution: vitamin B12, Methionine/Inositol/Choline Chloride (MIC) +vitamin B12 and MIC+vitamin B1+vitamin B12.

c) Your firm has never tested the potency or reconstitution time of your sterile lyophilized drug product Human Chorionic Gonadotropin 11,000IU prior to distribution.

9. Results of stability testing are not used in determining expiration dates.

Specifically, your firm lacked valid analytical and sterility data to support the following expiration dates applied to your sterile drug products:

a) 6-month expiration date assigned to HCG 11,000IU injectable.

b) 3-month expiration date assigned to MIC+B1+B12 25/25/25mg/mL+25mcg/mL+1000mcg/mL injectable.

c) 3-month expiration date assigned to Lysine HCL 200mg injectable.

d) 3-month expiration date assigned to Taurine 75mg/mL injectable.

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