DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	10/27/2014 - 11/19/2014* FEI NUMBER 3011116100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Andreas D. Dettlaff, Owner and CEO

FIRM NAME	STREET ADDRESS
Absolute Pharmacy, LLC	16011 N Nebraska Ave suite 103
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lutz, FL 33549-6158	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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) sterilization procedures currently being performed for the (b) (4) sterilization of all sterile drug products are not validated. This includes lack of validation data for the (b) (4)

B. Your pharmacist stated he does not have a written calibration program and could not provide calibration documentation for the following equipment:
   1. No documentation could be provided for your (b) (4) showing it has been calibrated and appropriately (b) (4).
   2. The (b) (4) used to sterilize finished drug product and components has not been (b) (4) during calibration.

OBSERVATION 2

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

Specifically, the media fills documented as being conducted by your pharmacist within the Buffer room and under the laminar flow hood were found to be deficient in that they do not accurately simulate

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current production processes and conditions that represent the most stressful/challenging conditions and optimize detection of any microbiological contamination. For example, there is no media fill data for your current operation of filling over (b) (4) multidose glass vials (10 mL) for a prepared batch that uses (b) (4) glass vials, stoppers, caps that are sterilized in-house.

OBSERVATION 3

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. I could not verify the claimed classifications for these areas based on the inadequate certification documentation that was provided to me during this inspection. For example:
   1. No leak test was performed on the HEPA filters inside your Ante room, Gowning room, and Buffer room.
   2. Air flow measurements were not conducted under dynamic conditions.
   3. No dynamic airflow pattern studies (i.e., smoke studies) have been performed in the laminar flow hood inside your Buffer room.

B. There is no continuous or at least periodically monitoring of air pressure differentials during production from the buffer room and ante room to the surrounding non-classified pharmacy area. Your pharmacist stated that he records a (b) (4) value from the magnehelic pressure gauges in the morning, which are located on the outside entrance into the ante room. These gauges are not viewable once inside the classified areas and no documentation could be provided showing that another employee is present during the formulation and filling of sterile drug products to monitor the magnehelic gauges.

C. No calibration documentation could be provided for the (b) (4) magnehelic pressure gauges to monitor pressure differentials inside the classified areas mentioned above.

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OBSERVATION 4

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

Specifically,

A. I could not verify that media used for collecting environmental samples is adequate to detect growth of violative organisms at low levels due to the following:
   1. Your pharmacist has not included disinfectant neutralizers (e.g., (b) (4)) when preparing in-house (b) (4) plates.
   2. Your pharmacist uses (b) (4) for growth promotion testing conducted for the media prepared in-house. No documentation could be provided showing this is an acceptable, consistent control.

B. Personnel monitoring within all classified areas is not adequate based on the following:
   1. Fingertip sampling uses the above mentioned inadequate media that is prepared in-house.
   2. Your pharmacist's gowning materials have never been sampled after preparation of sterile drug products and his gowning technique has not been qualified.

C. Air and surface sampling within all classified areas is not adequate based on the following:
   1. Sampling areas (air and surface) are not representative of the classified areas, since no scientific rationale could be provided for the current locations being sampled.
   2. Viable particulate sampling was not conducted inside your Ante room, Gowning room, Buffer room, and laminar flow hood under dynamic conditions.
   3. Viable surface sampling was not conducted inside your Ante room, Gowning room, Buffer room, and laminar flow hood during certification of these above classified areas.
   4. Non-viable particulate sampling was not conducted under dynamic conditions.
   5. Inadequately qualified in-house media (mentioned above) was used for sampling.

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OBSERVATION 5

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

Specifically,

A. Your pharmacist uses non-sterile disinfectants (e.g., (b) (4)) to clean the laminar flow hood where sterile drug products are prepared.

B. No sporicidal agent is used to clean your classified areas, including the laminar flow hood where sterile drug products are prepared.

OBSERVATION 6

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, gowning procedures are not being followed as well as gowning qualifications have not been conducted for your pharmacist that compounds sterile drugs in the Buffer room and under the laminar flow hood. For example, I observed inconsistent and inadequate gowning practices during this inspection as described below:

A. There is no demarcation of the dirty and clean side of the Gowning room entering into the Buffer room. I observed that the pharmacist walked all over the Gowning room during his gowning.

B. The pharmacist does not follow your SOP 9.100 "REQUIRED GARB FOR CLEAN ROOM FACILITY ACCESS", which states a sterile face mask should be worn. Your pharmacist stated he wears a face mask that is non-sterile while preparing sterile drug products. There is no evidence that your firm has purchased any sterile face masks to be used in the preparation of sterile drugs.

C. I observed the pharmacist handling and placing his face mask and goggles on his face prior to washing his hands.

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OBSERVATION 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) has not been validated. This process is used for all laboratory glassware used in the filling of sterile drug products.

B. The (b) (4) have not been validated. This process is used for finished product vials, rubber stoppers and caps used in the filling of sterile drug products.

C. Glass vials, caps, rubber stoppers, and beakers sterilized and/or depyrogenated in-house, are not identified in a way that would allow a trace back to the (b) (4) (b) (4)/batch.

OBSERVATION 8

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.

Specifically,

A. Your firm has not validated sterility and endotoxin testing to ensure substances in your product formulations do not interfere with the test.

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 (b) (4) drug products prior to distribution: Human Chorionic Gonadotropin, Melanotan II Acetate, and Sermorelin+Growth Hormone Releasing Peptide (GHRP)-2+GHRP-6.

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OBSERVATION 9

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically for the compounding of sterile drugs at your firm, you could not provide documentation stating what steps were completed, when they were completed, and by whom.

OBSERVATION 10

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, I could not verify hold times or the length of time it took to perform critical steps in the compounding of sterile drugs (e.g., Cyanocobalamin, Human Chorionic Gonadotropin, MIC+B12), such (b) (4) of the sterile drug products since batch production and control records were incomplete.

OBSERVATION 11

Each lot of a component, drug product containers, and closures liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

A. Your firm has no qualified vendor program and no documentation could be provided showing you have qualified any of your bulk drug substance (e.g., (b) (4) .) or component suppliers.

B. Your firm has not verified that any CoA test results are reliable for any incoming bulk drug substance used in the preparation of sterile drug products.

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OBSERVATION 12

A. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10). Specifically,

1. Your firm's labels affixed to the drug products do not contain the date for which the drug was compounded, as required by 503B(a)(10)(A)(iii)(V); and
2. The statement "Not for resale" is not present on certain drug product labels, as required by section 503B(a)(10)(A)(iii)(IX).

Examples include the following drug product labels: HCG Injection 5,000 USP Units/Vial; Cyanocobalamin USP 1,000mcg/mL; Sermorelin/GHRP-2/GHRP-6 10mg/3mg/3mg Vial; MIC +B12 25/50/50mg/mL + 20mcg/mL; and Melatonin II Acetate 10mg/Vial.

B. The containers from which the individual units of the drug are removed for dispensing or for administration do not adequately display the phone number to facilitate adverse event reporting (1-800-FDA-1088), nor does it display www.fda.gov/medwatch, as required by section 503B(a)(10)(B)(ii).

*** DATES OF INSPECTION:**
10/27/2014(Mon), 10/28/2014(Tue), 10/29/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed), 11/19/2014(Wed)

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