DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/09/2014 - 12/19/2014* FEI NUMBER 3010984686

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Abdul [nmi] Haneed, Owner

FIRM NAME	STREET ADDRESS
American Specialty Pharmacy	2743 W 15th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plano, TX 75075-7525	Producer of Sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

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

Specifically, on 12/9/2014, we observed Pharmacy Technician, (b) (6) process "Trimix - 9A Injectable Solution Injectable", Lot 12092014@1. The technician donned non-sterile garb (i.e. a disposable lab coat ("Isolation Gown"), shoe covers, a bouffant cap (hair net), a standard earloop face mask, and (b) (6) personal prescription eye glasses) to perform aseptic processing of a sterile drug product in an ISO 5 vertical laminar airflow (LAF) hood. In addition, the pharmacy technician entered the ISO 5 area with (b) (6) forehead, ears and neck containing facial hair exposed.

OBSERVATION 2

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

Specifically,

a. Personnel monitoring (PM) for each operator is conducted (b) (4) and not when each operator exits the clean room following preparation of sterile injectable drug products. Your firm is sampling fingertips of operators (b) (4) during the production day and not consistency after compounding is completed. In addition, your firm performs EMs and PMs during times of no production or clean room downtime instead of during production. SOP 3.030 Environmental Monitoring of the Clean Room Facility, version 2.0, effective 06/03/13, states (b) (4) .

b. Your firm does not perform Environmental Monitoring (EM) during each day of processing of sterile

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucas B. Leake, Investigator Lisa R. Jennings, Investigator	12/19/2014

injectable drug products. EM is performed every (b) (4) for viable air using (b) (4) settle plates, and surfaces using (b) (4) contact plates. Viable air sampling with (b) (4) settling plates is not performed actively during EMs, only passively.

c. Your firm uses (b) (4) plates for PM and EM, which are not incubated according to your SOP 3.030. PM and EM plates are incubated between 29-32°C. SOP 3.030 Environmental Monitoring of the Clean Room Facility, version 2.0, effective 06/03/13, states "Incubate all exposed samples for (b) (4) and then incubate for an (b) (4) There are no established action and alert limits. Time and/or dates are not documented for when plates are placed in and removed from incubator.

d. No positive or negative controls are completed for (b) (4) plates used. Your firm does not complete growth promotions. In addition, your firm does not maintain documentation or Certificate of Analysis for the (b) (4) plates.

OBSERVATION 3

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 has not validated the sterilization process for any drug products you prepare. Your firm prepares various drug products from bulk non-sterile active pharmaceutical ingredients (API) and excipients that are then (b) (4). The following products are prepared from non-sterile APIs: Testosterone cypionate, HCG, Nandrolone, Lipo B, M.I.C. B Complex, Edetate, Calcium Gluconate, Cyanocobalamin, Methylcobalamin, and Lipo B with C. In addition, your firm does not conduct (b) (4) for all batches.

b. Your firm has not validated the process you use to sterilize and depyrogenate non-sterile vials and stoppers to be used for injectable drug products.

c. Your firm's media fills do not simulate the aseptic fill process and do not simulate actual production process in that the worst case or most challenging conditions are evaluated. In routine production, your firm fills various vial sizes (10mL-100mL), syringes, and IV bags. Your firm prepares stock solutions, that are held in ISO 7 conditions, and are repeatedly manipulated to fill finished product orders. Your

firm will manipulate one stock solution up to (b) (4) . The media fills documented by your firm have the operator conducting a "PATT 2 - Personal Aseptic Technique Test". The test requires the operator to (b) (4)

d. On 12/09/2014, we observed the technician place his head under the hood, above the work surface, while processing a sterile drug product. The technician temporarily blocked the laminar air flow over a packaged single use syringe, a foil wrapped vial, and a syringe containing "Trimix - 9A Injectable Solution Injectable", Lot 12092014@1, to be (b) (4) .

OBSERVATION 4

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

Specifically,

a. Your firm uses (b) (4) , a non-sporicidal disinfectant, with reusable pads, to clean the floors and walls in the ISO 7 clean rooms. This disinfectants and these pads are not sterile.

b. Your firm's documentation is missing (b) (4) cleaning for 7/21-31/14. There is no assurance the clean room and hoods were cleaned during these days.

c. Your firm uses and rotates sporicidal disinfectant with a non-sporicidal disinfectant on the floors in the clean rooms on a random basis. Your firm uses (b) (4) instead of a sporicidal disinfectant in the ISO 5 LAF hood and the ISO 5 (b) (4) where drug products are prepared. Your firm does not document the cleaning solutions you use and when you use them.

d. On 12/09/14, we observed Pharmacy Technician, (b) (6) transfer materials including a single use syringe that remained in its packaging and stored in ISO 7 conditions, a vial wrapped in foil that was stored in a bin in ISO 7 conditions, and a syringe containing "Trimix - 9A Injectable Solution Injectable", Lot 12092014@1, from the ISO 7 clean room to the ISO 5 work surface without first sanitizing.

e. Your firm uses a (b) (4) for additional cleaning of your ISO 5 and ISO 7 clean rooms and surfaces. (b) (4) (b) (4)

(b) (4) . There have been no disinfectant effectiveness study.

OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

a. During certification, microbiological contamination was identified for viable air counts by an outside source in your ISO 5 LAF hood (3 cfu; limit (b) (4) and your ISO 7 "chemo room" (27 cfu; limit is (b) (4)) on 7/31/13 and 9/11/14, respectively. Your firm did not complete an investigation for these failures. No speciation for the microbial contamination was completed.

b. Your firm has not conducted smoke studies to date under dynamic conditions for the ISO 5 vertical LAF hood, which contains (b) work stations, used to produce sterile work products.

c. Pressure differential levels are not monitored continuously during production. Your firm records levels from the ISO 7 clean room (where ISO 5 hoods are located) to the ISO 7 ante room, and from the ISO 7 prep room to the outside unclassified area, randomly on a (b) (4) basis.

OBSERVATION 6

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

Specifically, your firm is not conducting routine sterility and/or endotoxin testing for all injectable drug products currently produced by your firm. Your firm (b) (4) for endotoxin and/or sterility testing.

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on your drug products. Your firm uses a third party consultant for suggested BUD. However, your firm places BUDs on the product that are past the suggested dates. The dates are not

supported by a stability testing program. For example,

a. The formula for Testosterone cypionate/propionate grapeseed Injection 80/20 200mg/mL has a BUD "estimated at 90 days". Lot # 04232014@3 was prepared on April 25, 2014 and has a BUD of July 24, 2014, which is 180 days after preparation.

b. The formula for Testosterone cypionate in sesame oil injection 100 mg/mL has a BUD "estimated at 90 days". Lot # 02112014@1 was prepared on February 11, 2014 and has a BUD of August 10, 2014, which is 180 days after preparation.

OBSERVATION 8

Drug products failing to meet established specifications are not rejected.

Specifically, on 6/10/2014, your firm received lab results indicating a failed Testosterone Cypionate assay test for the product, Sample #61415, "Testosterone Cypionate/Propionate Grapeseed Inj. 80/20; 200mg/mL", Lot 04232014@3. Your contract lab reported the following results:

1st replicate = 90.2%
2nd replicate = 89.7%

The 2nd replicate fell outside the (b) (4) specification range for Testosterone Cypionate. Your contract lab stated on its report, "The 89.7% result is out of specification(b) (4) ." Your firm did not conduct an Out of Specification (OOS) investigation before distributing this product on 7/15/2014.

OBSERVATION 9

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

Specifically,

a. Your firm does not document the preparation and (b) (4) of stoppers used for packaging sterile drug products.

b. Your firm does not document the preparation and (b) (4) of vials used for packaging sterile drug products.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/09/2014 - 12/19/2014* FEI NUMBER 3010984686

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Abdul [nmi] Haneed, Owner

FIRM NAME	STREET ADDRESS
American Specialty Pharmacy	2743 W 15th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plano, TX 75075-7525	Producer of Sterile Drugs

c. Your firm does not document on the Formula Worksheet the size and number of vials or syringes filled for each lot of sterile product manufactured. Your firm produces finished products from stock solutions without documenting this process. No batch and/or formula worksheets exist for these finished products.

d. Your firm does not document the (b) (4) (b) (4) or the results of the (b) (4) completed for every lot of sterile product manufactured.

For example, your firm did not document the (b) (4) (b) (4) or the results of the (b) (4) for the following sterile products:

1. 9/23/2014, "HCG, 1,000 units/mL for Injection Solution", 120mL, Lot 09232014@6
2. 9/29/2014, "Lipo B Injection Injectable", 200mL, Lot 09262014@8
3. 10/8/2014, "Cyanocobalamin 1mg/mL MDV 1mg/mL Injectable", 120mL, Lot 10082014@8
4. 10/15/2014, "M.I.C.B. Complex Injection", 300mL, Lot 10142014@5
5. 11/4/2014, "Glutathione 200mg/mL Inj Soln 200mg/mL Injectable", 100mL, Lot 11032014@2
6. 11/4/2014, "Edetate Calcium Disodium Inj Sol (PF) 30% Injectable", 700mL, Lot 11032014@10

Your firm does not (b) (4) .

*** DATES OF INSPECTION:**
12/09/2014(Tue), 12/10/2014(Wed), 12/11/2014(Thu), 12/12/2014(Fri), 12/15/2014(Mon), 12/16/2014(Tue), 12/18/2014(Thu), 12/19/2014(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucas B. Leake, Investigator Lisa R. Jennings, Investigator	12/19/2014