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	12/02/2014 - 12/12/2014* FEI NUMBER 3010589333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Richard E. Appling, Owner/President

FIRM NAME	STREET ADDRESS
Right Value Drug Stores, Inc.	122 Grapevine Hwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hurst, TX 76054-2406	Producer of sterile drug products

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, the general gowning attire for entry into the ISO 5/ISO 7 classified areas consists of the following: scrubs worn from outside the facility, a disposable lab coat, a single hair net, a single ear-loop face mask and booties. All are non-sterile. The operators also use a single pair of sterile gloves. On 12/2/14 we observed employee (b) (6) don the gloves inside the ISO 5 laminar flow hood. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing the drug product. We also observed employee (b) (6) with the wrist exposed between the end of the sleeve of the lab coat and the glove. Lot #12022014@7 of Dehydrated Alcohol 98% Injectable Solution was being prepared at the time.

OBSERVATION 2

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

Specifically,

a) Your firm is not performing environmental monitoring of the ISO 5 area every day that your firm is preparing drug products. SOP 3.030 Environmental Monitoring of the Clean Room Facility, version 2.0 effective 10/30/12, states that "surface samples of the Class 100 (ISO Class 5) area shall be taken (b) (4) ". Your firm is collecting viable surface samples (b) (4) in the ISO 5 hoods as stated in your procedure however, your firm is not taking the samples (b) (4) . Your firm takes surface samples on (b) (4) . (b) (4) (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO Margaret M. Annes Patrice S. Hall, CSO Patrice S. Hall	12/12/2014

Viable air monitoring is only performed every (b) (4) during certification of the rooms.

b) Your firm is not monitoring each operator working in the ISO 5 area and ISO 7 clean room each day that drug products are prepared. Your firm is currently sampling the fingertips of operators (b) (4) [redacted].

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 of the drug products that you prepare. Your firm prepares various drug products from bulk non-sterile APIs and excipients that are then (b) (4) (b) (4) [redacted] The drug products that are (b) (4) [redacted] include Testosterone pellets (various strengths), Estradiol pellets (various strengths) and Progesterone (Oil) 100mg/mL Injectable. Your firm has no documentation of the qualification of the (b) (4) [redacted] or how the (b) (4) for the pellets (b) (4) [redacted].

b) Your firm has not validated the process you use to sterilize and depyrogenate stoppers, vials and tubes to be used for injectable drug products.

c) Media fills performed by your firm with each of the operators that work preparing injectable drug products do not closely simulate actual production conditions or cover worst case or most challenging conditions. In routine production, your firm fills various size vials (2mL-100mL vials) as well as syringes, and batch sizes can be in excess of (b) (4) [redacted]. The (b) (4) [redacted] your firm is using has the operator filling (b) (4) [redacted] (b) (4) (b) (4)

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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 transfers sterile (b) (4) from the original container to a non-sterile container for use in the ISO 5 laminar flow hood and ISO 5 (b) (4) where drug products are prepared.

b) Your firm is using non-sterile wipes when disinfecting the ISO 5 laminar flow hood and ISO 5 biosafety cabinet.

c) Your firm is using (b) (4) for disinfection of the floors and walls in the ISO 7 clean room. Neither of these disinfectants is sterile.

d) Your firm is not using a sporicidal disinfectant in the ISO 5 laminar flow hood, ISO 5 (b) (4) (b) (4) and ISO 7 clean room where drug products are prepared.

OBSERVATION 5

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

Specifically, your firm does not conduct routine sterility or endotoxin testing for all injectable drug products currently produced or sterility testing for other drug products produced by your firm such as pellets and ophthalmic products. Your firm is selecting (b) (4) (b) (4) to be sent out for endotoxin and sterility testing.

In addition, your firm has recently implemented a procedure (change made August 26, 2014 to (b) (4) Standard Operating Procedures) that requires lots (b) (4) be tested for sterility and/or endotoxin. Your firm is not always following this procedure. For example,

a) Lot #10102014@13 of Testosterone Cyp (Sesame) 200mg/ml Injectable was made on 10/10/2014.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO Margaret M. Annes Patrice S. Hall, CSO Patrice S. Hall	12/12/2014

The exact number of vials filled is not documented on the Formula Worksheet but your firm has a hand written dispensing log to show that at least (b)(4) vials from this lot were dispensed. Your firm did not perform any testing on this lot.

b) Lot number: 09042014@13 of Testosterone Cyp (Sesame) 200mg/ml Injectable was made on 09/04/2014. The exact number of vials filled is not documented on the Formula Worksheet but your firm has a hand written dispensing log to show that at least (b)(4) vials from this lot were dispensed. Your firm did not perform any testing on this lot.

c) Lot #10232014@29 of Testosterone 100mg pellets was made on 10/23/14. There were (b)(4) pellets in this lot. Your firm did not perform any testing on this lot.

OBSERVATION 6

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. If your firm has documentation from your consultant about a suggested BUD, your firm is not always placing the suggested BUD on the drug products you prepare. The technician is to reference the formulation for the BUD to be assigned to a given drug product. For example,

a) The formula provided for Glutathione 200mg/mL Injectable states that the BUD for this product is "estimated to be 90 days". Lot #09162014@6 was prepared on 9/16/14. The BUD placed on the product was March 15, 2015, which is 180 days after preparation. Lot #10142014@17 was prepared on 10/14/14. The BUD placed on the product was April 12, 2015, which is 180 days after preparation. Lot #11142014@5 was prepared on 11/14/14 and the BUD placed on the product was May 13, 2015, which is 180 days after preparation.

b) The formula provided for Chorionic Gonadotropin 10,000U/10mL Injectable states that the BUD for this product is "estimated to be 30 days". Lot #10022014@17 was prepared on 10/2/14. The BUD placed on the product was December 1, 2014, which is 60 days after preparation. Lot #10152014@26 was prepared on 10/15/14. The BUD placed on the product was December 14, 2014, which is 60 days after preparation. Lot #11072014@3 was prepared on 11/7/14. The BUD placed on the product was

January 6, 2015, which is 60 days after preparation.

c) Your firm places a BUD of 6 months on all strengths of testosterone and estradiol pellets prepared by your firm. Your firm did not have a written stability protocol for these products. Your firm tested one 75mg pellet of testosterone and one 20mg pellet of estradiol. Testosterone is prepared in various strengths from 12.5mg-200mg and estradiol is prepared in various strengths from 6mg-80mg. The dimensions and weight of the pellets are different for each strength.

OBSERVATION 7

Each lot of a component, drug product container, and closure that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

a) Your firm is receiving and (b) (4) stoppers to be used for injectable drug products that are not depyrogenated. Your firm has not performed any testing of the stoppers to verify endotoxin content prior to (b) (4) and use.

b) Your firm is using (b) (4) for packaging Glutathione 200mg/mL Injectable. Your firm is not receiving a Certificate of Analysis with each lot received and used.

OBSERVATION 8

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 and tubes or the preparation and processing in the (b) (4) of vials that are to be used for packaging drug products prepared by your firm.

b) Your firm is not documenting in the Formula Worksheets the size and number of vials, syringes or tubes filled for each lot.

c) Your firm does not always document the (b) (4) used or the results of the (b) (4) performed.

For example, there is no documentation of the (b) (4) used or the results of the (b) (4) for lot #s 09162014@6 and 11142014@5 of Glutathione 200mg/mL Injectable and lot #s 11072014@3 and 11182014@24 of Chorionic Gonadotropin 10,000U/10mL Injectable. There are no results for the (b) (4) for lot #08222014@7 of Chorionic Gonadotropin 10,000U/10mL Injectable.

OBSERVATION 9

Batch production and control records do not include the specific identification of each batch of component used for each batch of drug product produced.

Specifically, your Formula Worksheet for Glutathione 200mg/mL Injectable states that the product is to be (b) (4) (b) (4) Your firm is actually using (b) (4) instead of (b) (4) There is no documentation in the Formula Worksheets of the actual (b) (4) used or the lot number.

OBSERVATION 10

The flow of components though the building is not designed to prevent contamination.

Specifically, your firm stores a (b) (4) (b) (4) that is used to prepare Glutathione 200mg/mL Injectable drug product in an unclassified area when not in use. When the (b) (4) is used, it is wiped down with (b) (4) and a non-sterile wipe and brought into the ISO 7 cleanroom. The (b) (4) is difficult to clean, labeling on the (b) (4) is fraying and there is adhesive residue on the (b) (4) from previous labeling.

OBSERVATION 11

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, your firm does not conduct routine testing for potency for all drug products produced by your firm. Your firm is selecting (b) (4) (b) (4) (b) (4) (b) (4) to be sent out for potency testing. For pellet products (i.e. testosterone and estradiol pellets) your firm is testing (b) (4)

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OBSERVATION 12

Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced.

Specifically, your firm does not include a copy of the actual labeling placed on finished drug product containers (i.e. vials & syringes) in the Formula Worksheet.

*** DATES OF INSPECTION:**
12/02/2014(Tue), 12/03/2014(Wed), 12/04/2014(Thu), 12/08/2014(Mon), 12/09/2014(Tue), 12/11/2014(Thu), 12/12/2014(Fri)

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