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	4/25/2017-5/12/2017* FEI NUMBER 3010589333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
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	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

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm routinely cleans stir bars and glass beakers with a (b) (4) (b) (4) before (b) (4) . Your firm has not validated this cleaning process to ensure that it is adequate to prevent cross contamination of drug substances. In addition, your firm has not verified that leftover residues of the (b) (4) are absent in the production of your drug substances.

OBSERVATION 2

Drug product production and control records, are not reviewed by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

Your firm's Quality Control Unit (QCU) is not fulfilling its duty and responsibility to ensure that the firm's batch production records are accurate and complete. I reviewed several batch records and observed numerous entry omissions such as quantity of sterile needles used, quantity of sterile syringes used, target number of units filled and lot numbers on batch records which should have been caught during QCU review of the batch production record.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Patty P Kaewussdangkul, Investigator 5/12/2017 X Patty P Kaewussdangkul Patty P Kaewussdangkul Investigator Signed by: Patty P. Kaewussdangkul -S	5/12/2017

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OBSERVATION 3
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your firm does not conduct preservative effectiveness tests on your multidose drug products to ensure that the preservatives intended to inhibit microbial growth are effective throughout the compounded drug product beyond use dates or expiration dates.

For example, no antimicrobial effectiveness test were conducted on the following multidose injectable products.

1) MIC/Methyl B-12/B-6/LIDO 25/50/50/1/100/10mg/ml Injection- Lot #02102017@4
2) Triamcinolone Ace/Lidocaine 40/2.5mg/ml Injection- Lot #01042017@12
3) Buprenorphine 1mg/ml Injection Sol Lot #02172017@3- Lot #02172017@3.

OBSERVATION 4
The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing and holding.

Specifically,

On 4/25/2017, I observed a Pharmacy Tech in the ISO7 cleanroom manufacturing Testosterone Cypionate in Sesame Oil 200mg/ml Lot #04252017@4 in the (b) (4) . I observed the employee (b) (4) the product (b) (4) . I asked the Pharmacy Tech to describe the process and was told that the manufacturing of this injectable drug product is (b) (4) consisting of (b) (4) (b) (4). However, upon review of (b) (4) completed batch records of Testosterone Cypionate in Sesame Oil, there is no documentation of this significant step where the product is (b) (4) (b) (4)

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(b) (4) . Your firm's batch records for Testosterone Cypionate in Sesame Oil 200mg/ml are not an accurate reflection of production.

OBSERVATION 5

Your outsourcing facility did not submit a report to FDA identifying a product compounded upon initially registering as an outsourcing facility as required by section 503B(b)(2)(A).

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

Specifically, the following information is not found on the container labels for some drug products you produce:

Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug product container labels that do not contain this information include:

- Estradiol Sterile Pellet
- Testosterone Pellet
- Methylprednisolone/Lidocaine Injectable
- M.I.C/Methyl B-12 Injectable

OBSERVATION 6

Your outsourcing facility did not submit a report to FDA upon initial registration identifying drug products that you compounded during the previous six months as required by section 503B(b)(2)(A).

***DATES OF INSPECTION**
4/25/2017(Tue),4/26/2017(Wed),4/27/2017(Thu),5/01/2017(Mon),5/02/2017(Tue),5/03/2017(Wed),5/04/2017(Thu),5/12/2017(Fri)

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