

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 10/28/2019-11/12/2019*
	FEI NUMBER 3010589333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Donald E. Prentiss, President of Operations

FIRM NAME Right Value Drug Stores, LLC dba Carie Boyd's Prescription Shop	STREET ADDRESS 8400 Esters Blvd , Suite 190
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CITY, STATE, ZIP CODE, COUNTRY Irving, TX 75063-2217	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility
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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

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

Specifically,

1. Room certifications conducted on June 22, 2019 by a third-party vendor established that the firm's ISO7/8 classified rooms all met their intended classifications however, room certifications were performed inadequately because they were conducted at rest and not under dynamic conditions to simulate normal routine production. Approximately (b) (4) batches of sterile injectable drugs products have been aseptically filled since June 22, 2019 in your ISO7 buffer rooms containing your ISO5 hoods.
2. No smoke studies have been conducted to evaluate the unidirectional airflow in the ISO5 LAFHs under dynamic conditions. Approximately (b) (4) batches of sterile injectable drug products have been aseptically filled in the ISO5 LAFHs.
3. Your firm failed to properly review the positive pressure of the ISO7 anterooms of your hazardous and non-hazardous sterile suites from 8/19/19 to 10/17/2019. Therefore, your firm was not aware of the consistent loss of pressure until 10/17/2019.

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patty P Kaewussdangkul, Investigator	Patty P Kaewussdangkul Investigator Signed by Patty P. Kaewussdangkul -S Date Signed 11-12-2019 07:39:06 X	DATE ISSUED 11/12/2019

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Specifically,

Your firm does not follow or record the contact times established by your disinfectant efficacy studies required to effectively clean the ISO5 LAFH/BSC and ISO7 buffer, ante and preparation rooms. On 10/28/2019, I observed (b) (4) cleaning procedures and observed the sterile technician disinfect the ISO5 LAFH with (b) (4) and immediately wipe dry with a sterile wipe. Your disinfectant efficacy studies state that contact time for (b) (4) is (b) (4). Therefore, there is no assurance that your cleaning process using various sterile cleaning agents are sufficient to achieve adequate levels of disinfection.

OBSERVATION 3

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component.

Specifically,

Your firm failed to conduct at least one specific identity test for the following drug components in lieu of complete testing when maintaining the supplier's certificate of analysis:

1. Methylcobalamin, Batch/Lot Number (b) (4) used in Chorionic Gonadotropin/Methyl-B12 1000U/1mg/1ml Injection Lot #09162019@2.
2. Human Chorionic Gonadotropin, USP Batch/Lot Number (b) (4) used in Chorionic Gonadotropin/Methyl-B12 1000U/1mg/1ml Injection Lot #09162019@2.
3. Estradiol (b) (4), Batch Number (b) (4) used in Estradiol 6mg Pellet, Lot #082819@02.

OBSERVATION 4

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There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

The Quality Control Unit (QCU) failed to thoroughly review batch production records for any unexplained discrepancy. There were batch production records missing specific identification numbers of major equipment used in production, missing pass/fail of ph calibration check, documentation of start times and stop times, incorrect visual examination reconciliation and lack of documentation of positive pressure of the ISO7 buffer and ISO7 preparation rooms. Batch production records with missing information was reviewed and subsequently released by the firm's QCU.

OBSERVATION 5

Procedures describing the handling of all written and oral complaints regarding a drug product are not established and written.

Specifically,

Your firm has a contract with (b) (4) to market, advertise and promote your sterile hormone pellets however, your firm has not established specific written procedures to ensure that all complaint received by (b) (4) (b) (4) regarding your sterile hormone pellets are forwarded to your firm. Therefore, your firm may not receive all written or oral complaints related to your sterile hormone pellets that need to be further investigated to determine if there are potential quality issues of your drug products and/or reportable to FDA in the event of an adverse drug reaction.

OBSERVATION 6

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Poor sterile gowning practices may allow sterile garb to become contaminated.

Specifically,

Gowning practices observed on 10/28/2019 by a Sterile Technician and a Quality Control Technician demonstrated that the technicians permit the sterile jump suit to repeatedly touch the floor which may contaminate the sterile jump suit prior to entry of the ISO7 buffer room containing the ISO5 LAFH. The practice of allowing the sterile jump suit to repeatedly touch the floor was observed again on 10/29/2019.

OBSERVATION 7

Your outsourcing facility has not submitted an adverse event report to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5).

Specifically,

On 09/26/2019, the firm received an unexpected possible life-threatening adverse drug reaction from the patient's doctor regarding implementation of the following sterile pellets:

1. Sterile Testosterone Pellet 25mg, Lot #102215-02.
2. Sterile Testosterone Pellet 50mg, Lot #101415-02.
3. Sterile Testosterone Pellet 87.5mg, Lot #102215-12.

As of 10/31/2019, the adverse event reaction to these drug products have not been reported to FDA within 15 calendar days from 09/26/2019 required.

OBSERVATION 8

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You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503(B)(d)(2).

Specifically, you compound drug products that:

- a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
- b) are not identical or nearly identical to an approved drug but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

1. Dyclonine (mint) * Office Use* 0.5% Solution
2. Dyclonine (mint) * Office Use* 1% Solution

OBSERVATION 9

Your outsourcing facility has not submitted a report to FDA identifying products compounded during the previous six months as required by section 503B(b)(2)(A). Specifically, the following products were compounded and not identified on your report dated July 3, 2019:

4. HCG Methylcobalamin B12 1000IU Injection
5. Testosterone Pellets- 25mg, 37.5mg, 50mg, 100mg and 200mg
6. Estradiol Pellets- 6mg, 10mg, 12.5mg and 15mg
7. Testosterone/Anastrozole Pellets -75mg/4mg, 100mg/4mg
8. Testosterone cypionate/ Testosterone propionate 200mg/10mg Injection

***DATES OF INSPECTION**

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10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed), 10/31/2019(Thu), 11/01/2019(Fri),
11/04/2019(Mon), 11/07/2019(Thu), 11/08/2019(Fri), 11/12/2019(Tue)

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