DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	6/7/2022-6/27/2022* FEI NUMBER 3010589333

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

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

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

a) Your firm did not perform an investigation into all environmental monitoring excursions that occurred in the ISO 5 Biological Safety Cabinet (BSC), including performing a product impact assessment. The excursions include the following.

i. Lot # (b) (4) of Testosterone Cypionate 200mg/mL Injection compounded and aseptically filled on 06/02/2021 - One (1) CFU recovered for an active air sample in the ISO 5 BSC. The organism recovered was identified as *Staphylococcus lugdunensis*. The lot was released and distributed (b) (4) /30mL vials).

ii. Lot # (b) (4) of Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL Injection compounded and aseptically filled on 07/16/2021 - One (1) CFU recovered for an active air sample in the ISO 5 BSC. The organism recovered was identified as *Penicillium chrysogenum*. The lot was released (b) (4) 10mL vials) and distributed.

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	Margaret M Annes, CSO Jamirya S Weatherly, Investigator	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-27-2022 07:22:25	6/27/2022

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iii. Lot # (b) (4) of Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL Injection compounded and aseptically filled on 08/10/2021 - One (1) CFU recovered for a surface sample in the ISO 5 BSC. The organism recovered was identified as *Paenibacillus turicensis*. The lot was released and distributed (b) (4) 30mL vials).

b) There is no assurance environmental monitoring excursions are thoroughly investigated to prevent reoccurrence. Your firm does not always document activities and evaluations conducted as part of investigations and/or corrective/preventive actions (CAPA) of environmental monitoring excursions. Since May 2021, your firm has had numerous organisms (bacteria and fungi) identified in active air and surface samples in cleanrooms located in the (b) (4) Suite where aseptically filled drug products are made and the (b) (4) Suite where (b) (4) sterilized hormone pellets are made.

Your firm has no documentation to show an evaluation of all potential root causes such as the storage of active air samplers in a (b) (4) in an unclassified area or the failure of technicians to wipe down the outside of the (b) (4) prior to placing them in the cleanroom suites.

Your firm has also not evaluated nor demonstrated that the current process to disinfect and sterilize the sampling head of the active air sampler is adequate.

Examples of organisms recovered include the following.

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i. Your firm has recovered *Cladosporium cladosporioides* at least 20 times from August 2021 to May 2022 in both surface and active air samples in Rooms (b) (4) (ISO 7 Ante Room where (b) (4) occurs), (b) (4) (ISO 7 cleanroom where ISO 5 BSCs are located), (b) (4) (ISO 7 Ante Room where (b) (4) occurs), (b) (4) (ISO 7 Room where hormone pellets (b) (4)), and (b) (4) (ISO 7 Room where hormone pellets (b) (4)).

ii. During the week of 11/29/2021, your firm recovered *Sporobolomyces* (genus)/*Sporidiobolus johnsonii* in active air samples taken in (b) (4) (ISO 7 Ante Room), (b) (4) (ISO 7 Room where hormone pellets (b) (4) (b) (4) (ISO 7 where compounding of bulk drug products occurs before (b) (4)) and (b) (4) (ISO 7 cleanroom where ISO 5 BSCs are located).

OBSERVATION 2

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

Specifically,

a) Your firm does not conduct active viable air sampling in the ISO 5 areas during production of aseptically filled drug products. Active viable air samples are taken after production, when the ISO 5 BSC is empty and the product has already been filled into vials. On 06/07/2022, we watched the QC employee perform active viable air sampling after the production of lot # (b) (4) of Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL Injection, when the hood was empty and no product was being filled.

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Your firm has no documented justification for the orientation of the non-viable particle continuous monitoring probes located in the ISO 5 biological safety cabinets (BSC). The placement of the (b) (4) is not fixed and is bumped and moved during production and cleaning of the BSCs. Orientation of the (b) (4) is not directed into the flow of air during monitoring. Your firm cannot demonstrate that the orientation and placement of the probes provides a meaningful sample.

For example, on 06/08/2022 we saw the (b) (4) laying on the surface of the ISO 5 BSC (b) (4) in Room (b) (4) during the production of lot # (b) (4) of Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL Injection. On 06/09/2022, your firm attached the (b) (4) to a stand however, the (b) (4) did not stay in a fixed location and tilted towards the back of the ISO 5 BSC.

In addition, the protocol and executed report for the Installation Qualification and Operational Qualification (IQ/OQ) of the system used for non-viable particulate monitoring (continuous monitoring) as well as monitoring of temperature, humidity and differential pressure does not have signatures and dates indicating review and approval. The protocol and report also do not document the location and positioning of the non-viable particulate monitoring probes during the OQ.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

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a) Smoke studies performed in the ISO 5 Biological Safety Cabinets (BSC) in Room (b) (4) are not representative of all activities performed. For example, on 06/08/2022 we watched the (b) (4) and filling of lot # (b) (4) of Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL Injection. We saw (b) (4)

The smoke studies performed in November 2019 had an approximately (b) (4) In addition, the process of filling the vials did not include the use of the pump and did not simulate the actual filling operations we witnessed during the inspection.

In the smoke studies conducted on 04/30/2021, there is not enough smoke generated to visualize airflow in the ISO 5 BSC and they did not simulate the actual filling operations we witnessed during the inspection.

Your firm does not have written and approved protocols or procedures for how the smoke studies should be conducted nor reports regarding the review and approval of the smoke studies.

b) Your firm has no documentation to show the ISO 5 biological safety cabinets and laminar flow hoods where sterile drug products are (b) (4) and filled into vials were certified under dynamic conditions.

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c) Your firm does not check the pH nor conduct growth promotion of the media prepared by your firm for use in media fills (aseptic process simulation).

OBSERVATION 4

Drug product closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, your firm receives in non-sterile (b) (4) caps to be used for the packaging of sterile hormone pellets in glass vials. Your firm has no documentation to show that these caps have been cleaned and (b) (4) before receipt. Your firm has no process to clean and (b) (4) them before use in packaging.

OBSERVATION 5

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the HEPA filter (b) (4) used to remove dust from the pellet presses as well as from hormone pellets at the time of vialing are not sanitized appropriately and their design does not allow for adequate storage and protection of the end of the (b) (4) that touches the pellets, when not in use. Your firm's written procedure SOP 6.030 Pellet Production, does not provide specific instructions on how to store or protect the end of the (b) (4) or what to do if the end of the (b) (4) touches the floor. On 06/09/2022 during the vialing of lot # (b) (4) of Testosterone 200mg pellets, we saw the (b) (4) on the HEPA filter (b) (4) fall to the floor when the operator tried storing it after use. The (b) (4) was not cleaned and sanitized before being used again. The end of the (b) (4) touches the pellets through a (b) (4) when they are being (b) (4).

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OBSERVATION 6

Batch production and control records do not include dates of each significant step in the manufacture and processing of the batch for each batch of drug product produced.

Specifically, the batch record for Testosterone Cypionate 200mg/Testosterone Propionate 10mg/mL states to (b) (4) For the (b) (4) batch, this would equate to approximately (b) (4). Your firm documents the beginning of this (b) (4) of mixing (b) (4) as the batch record states. For example, for lot # (b) (4) it took approximately (b) (4) to weigh and add all ingredients. The solution was then mixed for approximately (b) (4). Your firm has no documentation to show that the process has been validated.

OBSERVATION 7

Written procedures are lacking which describe in sufficient detail the receipt, identification, sampling, testing, approval and rejection of components.

Specifically, your firm is using a (b) (4) to make non-sterile drug products such as dental gels. Your firm does not perform testing (analytical or microbiological) to show the (b) (4) at least/at minimum meets the specifications for (b) (4). The quality of the (b) (4) is not appropriate for pharmaceutical use.

OBSERVATION 8

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Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a) Your firm is not bracketing the range of use when calibrating the analytical balances used to weigh raw materials and perform in process weight checks of hormone pellets. For example, your firm weighs hormone pellets as part of in-process testing and release testing (weight variation). The pellets weigh from (b) (4) (lowest allowed weight for (b) (4) to (b) (4) (highest weight for (b) (4)). There are (b) (4) analytical balances used for weighing the pellets. The first test point is (b) (4) on (b) (4) and (b) (4) on (b) (4) .

b) Your firm does not have a written procedure or documentation for the calibration of the (b) (4) used for non-sterile drug products. (b) (4) is an in-process test and can also be part of the release testing for dental gels such as Lidocaine/Prilocaine/Tetracaine/Phenylephrine 10/10/4/2% Aqueous Gel.

OBSERVATION 9

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically,

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six-month period. Specifically, the following products were compounded and not identified on your report dated [December 29, 2021 (2021-2)]:

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- Benzocaine/Lidocaine HCl/Tetracaine (R&D lot, not distributed)
- Dyclonine HCl/Diphenhydramine HCl (R&D lot, not distributed)
- Ketoconazole/Zinc Oxide topical (R&D lot, not distributed)
- Ketorolac tromethamine/magnesium (R&D lot, not distributed)
- Testosterone 100 mg/Triamcinolone (R&D lot, not distributed)
- Testosterone 12.5 mg with 0.02% Triamcinolone pellets (R&D lot, not distributed)
- Testosterone 50 mg with Triamcinolone (R&D lot, not distributed)
- Testosterone 55 mg with 0.02% Triamcinolone pellets (R&D lot, not distributed)
- Methylprednisolone/Lidocaine 80mg/2.5mg/mL (produced, but not distributed during this time period)

Similarly, your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the six-month reporting period previous to the one above. Specifically, the following products were compounded and not identified on your report dated [July 1, 2021 (2021-1, but mistakenly labeled reporting period 2020-1 in the FDA's reporting system)]:

- Promethazine 25 mg/GM (R&D lot, not distributed)
- Dyclonine HCl/Diphenhydramine HCl (R&D lot, not distributed)
- Nifedipine/Allantoin topical (R&D lot, not distributed)
- Testosterone 100 mg with Triamcinolone HCl (R&D lot, not distributed)
- Testosterone 100 mg/ Estradiol 12.5mg (R&D lot, not distributed)
- Testosterone 100 mg/ Estradiol 15 mg (R&D lot, not distributed)
- Testosterone 12.5 mg with 0.02% Triamcinolone HCl (R&D lot, not distributed)
- Testosterone 200 mg with 0.02% Triamcinolone HCl (R&D lot, not distributed)
- Testosterone 55 mg with 0.02% Triamcinolone HCl (R&D lot, not distributed)

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OBSERVATION 10

The container labels of your outsourcing facility's drug products are deficient.

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

Route of administration.

Examples of drug product containers that do not contain this information:

- Estradiol 20 mg (with 1.6% stearic acid) pellet (Lot # (b) (4));
- Testosterone 87.5 mg (with 5.5% stearic acid) pellet (Lot # (b) (4));
- Testosterone 100 mg (with 5.5% stearic acid) pellet (Lot # (b) (4)); and
- Testosterone/Anastrozole 100 mg/5 mg (with 5.5% stearic acid) pellet (Lot # (b) (4)).

***DATES OF INSPECTION**

6/07/2022(Tue), 6/08/2022(Wed), 6/09/2022(Thu), 6/10/2022(Fri), 6/13/2022(Mon), 6/14/2022(Tue), 6/15/2022(Wed), 6/27/2022(Mon)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."