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	5/28/2024-6/21/2024* FEI NUMBER 3010589333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Donald E. Prentiss, COO	
FIRM NAME Carie Boyd Pharmaceuticals	STREET ADDRESS 8400 Esters Blvd Ste 190
CITY, STATE, ZIP CODE, COUNTRY Irving, TX 75063-2217	TYPE ESTABLISHMENT INSPECTED 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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A. Your firm's smoke studies and (b) (4) cleanroom recertification reports, document ISO 5 Biological Safety Cabinets (BSC) in Room H300 are performed in the dynamic state. However, during a review of your firm's January 2024 ISO 5 BSC smoke studies, there were found not to be in a dynamic state. For example, your firm's dynamic smoke studies failed to include compounding technician performing any bulk drug (b) (4) activities, bulk bag transfers, vial setup, bulk bag setup, vial filling, vial transfers, bulk bag exchanges, environmental monitoring sampling, and other critical production interventions occurring during filling that may alter first and unidirectional air flow within your firm's ISO 5 BSCs affecting the sterile finished drug product and patient safety.

B. Your firm's media fill procedure, Aseptic Process Simulation (APS), 5.400 (Section 5.4) documents, "Minimum number of units to be filled: (b) (4) units per person". However, normal sterile drug vial filling performed by a technician, range from (b) (4) vials depending on bulk production batch and vial size. Your firm's media fill vial quantity per technician fail to reflect the most challenging condition as part of your firm's technician qualification process.

This is a repeat deficiency.

OBSERVATION 2

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

Specifically,
Your firm's procedure, Deviation Management, 4.011 is not adequately implemented. For example:

A. Your firm's management failure to initiate a deviation in a timely manner and conduct a risk assessment for in-process batches stored in the DEA Caged Storage area affected by the temperature and relative humidity excursion occurring on 5/28/2024, caused by the power outage. Your firm's Director of Quality reported your firm performed a detailed cleaning of its ISO Classified Cleanroom. However, there was no containment activities performed to prevent further processing of in-process drug product located in the caged area.

B. Deviation DEV-2023-017 dated 5/18/2023, reported an issue concerning your firm's Component Receiving Logbook not being used as required by your written procedure, Inventory Management, 4.060. As a corrective action, your firm initiated, Document Change Control, 2023-075 for the procedure, Inventory Management to add clarity to the responsibilities section. The deviation was closed on 6/20/2023.However, on 5/31/2024, your firm's procedure, Inventory Management, 4.060, Version 6 effective date 12/01/2021, was provided and reviewed, revealing no updates. Your firm Director of Quality reported a document change control, DC-2023-075 was initiated to address and track the procedure update. However, your firm failed make written updates, approve, implement, and conduct training for this corrective action.

C. Deviation DEV-2023-023 dated 6/12/2023, reported 5 vials being found unlabeled in a partial box of released pellets. Your firm documented the issue as being human error related. However, your firm failed to expand the investigate into potential errors in the number of printed labels and possible method used to affix labels to the vials.

D. Deviation DEV-2023-073 dated 12/20/2023: and DEV-2023-074 dated 12/20/2023, reported during filling within ISO 5 BSC environmental monitoring, (b) (4) hood monitoring within Room H-300, Total Airborne Particles exceeded ISO 5 specification

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(b) (4) microns (b) (4) particles per cubic foot) with maximum measured value of 3956 particles per cubic feet while producing sterile lot, Testosterone Cypionate, 200mg/mL with Miglyol ® 812N 30mL, Lot Number (b) (4). All (b) (4) filled vials filled in the BSC on (b) (4) BSC from the bulk batch bag was discarded. The sterile bulk bag was transferred to a different BSC, located on the (b) (4), and the vial filling from the bag was continue. By the start of this inspection, no investigation had been initiated to identify reason for (b) (4) ISO 5 BSC performance issues.

This is a repeat deficiency.

OBSERVATION 3

Equipment for adequate control over humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your firm's DEA Caged storage areas used for quarantine products, quarantine chemical, and finished product lack a written document defining environmental specifications for temperature and relative humidity. This storage also contains finished drug products, controlled drug components, and in-process quarantine drug product being stored awaiting additional processing and distribution. Deviation Number, DEV-2024-046 date 5/29/2024, documented a relative humidity excursion caused by a power outage and identified the following drug products as being in-process and impacted since being stored within the DEA Lockup Cage:

A. Testosterone 200MG Pellets, Lot # (b) (4) BUD 05/14/2025, (b) (4) pellets
B. Testosterone 200MG Pellets, Lot # (b) (4) BUD 05/13/2025, (b) (4) pellets
C. Estradiol 12.5MG Pellets, Lot # (b) (4), BUD 5/17/2025, (b) (4) pellets

These pellet batches were not stored in sealed vials. The pellets were bulk packaged within a (b) (4) (b) (4) covered with a (b) (4) material and (b) (4). Your firm's Director of Quality reported

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no scientific study had been performed to access environmental impact on in-process pellets stored in the caged area using the bulk drug storage method.

OBSERVATION 4

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically, your firm failed to provide documents and records to support the assigned expiry dates for (b) (4) glassware used in aseptic processing. The Director of Quality reported that no studies or laboratory test data were conducted to justify the (b) (4) expiry. Additionally, during a walk-through of your firm's (b) (4) glassware storage room, Non-classified (b) (4) (negative pressure storage room), within your firm's (b) (4) glassware cabinet, (b) (4) (b) (4) ((b) (4)) used for compounding (b) (4) drug products, were assigned a (b) (4) expiry. Furthermore, in the same storage cabinet, a (b) (4) (b) (4) used in the compounding of sterile drug products was found without a documented (b) (4) date, expiry, or employee initials on the top of the (b) (4) cover.

This is a repeat deficiency.

OBSERVATION 5

Drug product containers and 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 failed to ensure pellet caps are endotoxin free prior to their intended use. Your firm's validation report, GS-2023-025 (b) (4) by Rinsing of Pellet Vial Caps - Process Validation dated 7/03/2023 document sample result failures, achieving only a 1 to 2 Log reductions (Specification (b) (4)) in laboratory testing. Your firm has implemented and currently using procedure, (b) (4) by Rinsing of Pellet Vial Caps, 6.043, Version 2, Effective 11/14/2022 for the (b) (4) of pellet caps in the absence of additional laboratory testing, following its original

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validation failure.

This is a repeat deficiency.

OBSERVATION 6

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

Specifically, a list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of your drug product labels that do not contain this information:

- Ketoconazole 2% (b) (4) Cream
- Testosterone Cypionate 200 mg/ml injection
- Testosterone Cypionate 200 mg/ml + Testosterone Propionate 10 mg/ml injection.

This is a repeat deficiency.

***DATES OF INSPECTION**

5/28/2024(Tue), 5/29/2024(Wed), 5/30/2024(Thu), 5/31/2024(Fri), 6/03/2024(Mon), 6/04/2024(Tue), 6/05/2024(Wed), 6/06/2024(Thu), 6/07/2024(Fri), 6/21/2024(Fri)

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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."