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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 8/18/2025-9/5/2025* |
| | FEI NUMBER<br>3014982757 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel D. DeNeui, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| FARMAKEIO OUTSOURCING LLC | 920 S Kimball Ave Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Southlake, TX 76092-9019 | TYPE ESTABLISHMENT INSPECTED<br>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

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 failed to adequately investigate and initiate corrective and preventive actions for CAPA #, CAPA-2025-0002 dated 03 Apr 2025, which documents metal shavings being found during Testosterone/Triamcinolone Acetonide granulation resulting from a worn impeller shaft seal and metal fit ring. Your firm failed to identify and or confirm how long the shaft and ring had been worn and or expand the investigation beyond immediately manufactured batches, and into other manufactured finished sterile implantable distributed pellets, e.g., Testosterone Pellet (Product Strengths: 200mg, Lot 3203, Expiry 2/17/202026; 87.5mg, Lot 3193, Expiry 2/17/2026; 62.5mg, Lot 3180, Expiry 2/17/2026; & 50mg, Lot 3179, Expiry 2/17/2026) from Testosterone Granulation Lot (b) (4) Expiry 2/17/2026. Additionally, your firm's metal detection system for finished pellets was not operational until May 19, 2025, metal detection performance qualification (PQ) quality unit approval date. Before this date, no finished pellets underwent metal detection as part of its manufacturing process. The (b)(4) intermediate product, which is (b)(4) and then processed into pellets, was visually inspected, packaged, (b)(4) sterilized, and distributed without this critical check.

B. Your firm failed to adequately investigate received customer complaints. For example:
   1. COMP-2025-0023 dated 6/20/2025 and COMP-2025-0018 dated 5/23/2025, documents received complaints for cracked pellets. Your firm's failed to adequately investigate the

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source of cracked pellets within your firm's manufacturing process and expand investigation into all area including distribution.

2. COMP-2025-0002 dated 1/04/2025 - documents received complaint for incorrect pellets distributed. Your customer ordered a (b)(4) count packages box of Testosterone/ Triamcinolone Pellet (25MG/5MCG), but received Estradiol 25mg pellets. Your firm failed to adequately investigate the product's secondary packaging mix-up.

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**OBSERVATION 2**

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. During a review of your firm's batch record for Product ID # 364, Testosterone/ Triamcinolone Acetonide Pellet (200mg/40mcg), Lot # 3131, including laboratory test chromatograms, unknown/unidentified peaks were found during sampling testing prior to and following (b)(4) sterilization. Your firm's management reported they are aware of the unknown peaks and at the time of this inspection is working with a contract testing laboratory to identify and determine the pharmacological activity of the foreign peaks for the Testosterone/Triamcinolone Acetonide pellets. Your firm released and distributed this lot and continued producing and distributing more lots of this pellet product without identifying the unknowns.

B. Testosterone/Triamcinolone Acetonide Granulation 95%/0.02 % Chemical Lot (b) (4) Expiry 1/29/2026, Qty. (b) (4); and Lot #(b) (4) Expiry 2/03/2026, Qty. (b)(4) were used to produce Product ID # 364, Testosterone/Triamcinolone Acetonide Pellet (200mg/ 40mcg), Lot # 3131. A review of the granulation batch record found your firm failed to establishment scientifically sound and appropriate specification for the addition of the API, Triamcinolone Acetonide to the batch in the amount of 0.3g (Specification (b)(4) ) instead of (b) (4) as expected to be in the final formulation of the pellet. This was documented in both granulation batches. This is (b)(4) in

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excess.

C. After metal shavings were found in your Testosterone/Triamcinolone Acetonide granulation lots, your firm decided to scan pellets through a metal scanner. However, the sample size of the batch was determined using (b) (4) Standard (b) (4) : A sample size, (b)(4) pellets for batch size (b)(4) to (b)(4) was selected using General Inspection Level III. Your firm failed to comply with USP <790>, which allows AQL, as a sampling requirement at batch release to be conducted "After 100% Manufacturing Inspection".

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**OBSERVATION 3**

Each batch of controlled-release dosage form drug product is not laboratory tested to determine conformance to the specifications for the rate of release for each active ingredient.

Specifically, your firm failed to require or perform dissolution testing on each batch of controlled-release dosage form drug product. The drug product is not laboratory tested to determine conformance to the specifications at a rate of release for each active ingredient that is reproducible. At the time of this FDA inspection, your firm failed to adequately define a dissolution specification for the following pellet product families.

A. Testosterone Regular Release Pellet (Contains no Ethylcellulose excipient); Product Strengths: 200mg & 50mg; BUD 365 days.
B. Testosterone Pellet (Contains Ethylcellulose excipient); Product Strengths: 200mg, 100mg, 87.5mg, 62.5mg, 50mg, 37.5mg, 25mg, & 12.5mg; BUD 365 days.
C. Testosterone/Triamcinolone Acetonide Pellet; Product Strengths: 200mg/40mcg, 100mg/20mcg, 87.5mg/17.5mcg, 62.5mg/12.5 mcg, 50mg/10mcg, 37.5mg/7.5mcg, 25mg/5mcg, & 12.5mg/2.5mcg; BUD 365 days.
D. Estradiol Pellet; Product Strengths: 25mg, 20mg, 18mg, 15mg, 12.5mg, 10mg, & 6mg; BUD 365 days.

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## OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and of adequate size to facilitate operations for its intended use.

Specifically,

A. Your firm's (b)(4) Systems, (b) (4) Metal detection System qualification failed to show the equipment is adequately designed and sized to facilitate operations for its intended use. During a review of your firm's (b)(4), Pharmaceutical Metal Detector Performance Qualification Manual, Approval Date 5/192025, the PQ acceptance criteria was found inadequate, and failed to require specifications for the test equipment and materials. For example, within Section 7.2.2, Acceptance Criteria, your firm failed to quantify (based on (b)(4) acceptance and reject allowances for (b)(4), and (b)(4) tablets or test samples. Additionally, in Section 7.2.3, Test Equipment and Materials, your firm failed to quantify how many total samples shall be used for each type (i.e., (b)(4), and (b)(4)) as part of the production equipment qualification. Your firm COO reported a total of (b)(4) pellets and (b)(4) pellet was used in the study for each contaminate pellet type.

B. During a review of your firm initiated CAPA-2025-002, Finding foreign material - granulation process, your firm documented the root cause for the origin of the foreign material resulted from the granulator impeller shaft grinding against the (b)(4). A preventive maintenance (PM) was added for the (b)(4) Lab Grinder to include an inspection the (b)(4) before running the granulator. Your firm failed to include in the PM an inspection of the impeller shaft and the (b)(4) for excessive wear based on investigation findings.

## OBSERVATION 5

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

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Specifically, during a review of your firm's batch record for Testosterone/Triamcinolone Acetonide Pellet 200mg/40mcg, Lot 3468, Expiry 7/23/2026, Sections 2.3.1.3 - 2.3.1.5, document pellets being processed through the (b)(4) Systems, (b) (4) Metal detection System. Section 2.3.1.5, states (b)(4) ". Your firm's batch record fail to define and document the type of each sample shall be used, number of control samples, and the frequency during pellet processing to ensure proper performance.

***DATES OF INSPECTION**

8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 9/05/2025(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."