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	6/1/2022-6/10/2022* FEI NUMBER 3014982757

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel D. DeNeui, CEO	
FIRM NAME FARMAKEIO OUTSOURCING LLC	STREET ADDRESS 920 S Kimball Ave Ste 100
CITY, STATE, ZIP CODE, COUNTRY Southlake, TX 76092-9019	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 WE OBSERVED:

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,
Your Pharmacist/Quality Director released lots of hormone replacement pellets for distribution without laboratory testing data to demonstrate that established final specifications such as sterility, potency and endotoxin limits were met prior to release for distribution. For example,

- Testosterone/Triamcinolone Acetonide Pellet 200mg/40mcg, Lot #(b) (4), BUD: 2023-05-04 shipped and delivered to a customer in (b) (4), (b) (6).
- Estradiol Pellet 25mg, Lot #(b) (4) BUD: 2023-05-12 shipped and delivered to a customer in (b) (4), (b) (6).

In addition, your firm's SOP entitled, "Finished Product Release Testing" SOP QMS-3015 Effective 06/01/2019 is silent regarding this practice of releasing finished product for distribution in absence of complete testing data.

OBSERVATION 2

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,
Your firm's places (b) (4) beyond use date/expiration date on your Testosterone pellets containing

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Triamcinolone in various strengths however, your bracketed stability data shows that the Triamcinolone was consistently subpotent when tested initially and at the following time points: (b) (4) and (b) (4)

OBSERVATION 3

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

Specifically,

Your firm's current potency specification of (b) (4) set for Triamcinolone instead of the scientifically recognized (b) (4) is not scientifically sound or appropriate which allowed drug products containing sub potent or super potent Triamcinolone to be released and distributed to patients. From 6/1/2021 to time of inspection there were at least (b) (4) ots of Testosterone/Triamcinolone pellets where Triamcinolone did not meet the standard potenc ecification of (b) (4)

OBSERVATION 4

Written procedures are not drafted, reviewed and approved by the appropriate organizational units.

Specifically,

Your firm failed to document the changes to the quantity of Triamcinolone acetonide within the granulation batch records for Testosterone/Triamcinolone (b) (4) for the following Lots: (b) (4) (b) (4) without appropriate review and approval by the Quality Unit.

OBSERVATION 5

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

Specifically,

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The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). All your drug products have a National Drug Code (NDC) which is currently not listed on all your compounded drug product labels. At time of inspection, Testosterone/Triamcinolone Pellet 200mg/40mcg is the only drug that lists the NDC on its container/product label.

OBSERVATION 6

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

Specifically,

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

- Directions for Use – ~~Storage conditions,~~ Dosage form and route of administration per 503B(a)(10)(B)(iii).

OBSERVATION 7

Processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) Your firm's ISO7, ISO8 classified areas are certified by a third-party vendor on (b) (4) basis however, microbial testing was not performed during the last two room certifications to ensure that the classified areas used to prepare, form, package and label your hormone replacement pellets meet microbial specifications of their intended classifications.

b) Your firm conducts environmental monitoring of the ISO7 areas dedicated to manufacturing, pelletizing, packaging and labeling of your drug products however, it is being performed inadequately. For example, non-viable monitoring is not performed during operations, surfaces are disinfected (b) (4) to sampling and glove monitoring is conducted on (b) (4) basis.

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***DATES OF INSPECTION**
6/01/2022(Wed), 6/02/2022(Thu), 6/03/2022(Fri), 6/06/2022(Mon), 6/08/2022(Wed), 6/10/2022(Fri)

Steven A. Brettler -S
Digitally signed by Steven A. Brettler -S
Date: 2022.06.14 10:45:49 -04'00'

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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."