

**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 10/22/2019-10/30/2019* FEI NUMBER 3014982757
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cody Boatman, COO

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 Prescription Drug Manufacturer 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**

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

- Labels for the following drug products do not contain this statement include:

Drug Name	Drug Form	Drug Strength
TESTOSTERONE / TRIAMCINOLONE	PELLET	100MG / 20MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	200MG / 40MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	87.5MG / 17.5MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	62.5MG / 12.5MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	50MG / 10MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	37.5MG / 7.5MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	25MG / 5MCG
TESTOSTERONE / TRIAMCINOLONE	PELLET	12.5MG / 2.5MCG
ESTRADIOL	PELLET	6 MG
ESTRADIOL	PELLET	10MG
ESTRADIOL	PELLET	12.5MG
ESTRADIOL	PELLET	15MG
ESTRADIOL	PELLET	18MG
ESTRADIOL	PELLET	20MG
ESTRADIOL	PELLET	25MG
TESTOSTERONE	PELLET	12.5MG
TESTOSTERONE	PELLET	25MG
TESTOSTERONE	PELLET	37.5MG
TESTOSTERONE	PELLET	50MG
TESTOSTERONE	PELLET	62.5MG
TESTOSTERONE	PELLET	87.5MG
TESTOSTERONE	PELLET	100MG
TESTOSTERONE	PELLET	200MG

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Francis A Guidry, Investigator (Biotechnology) 	DATE ISSUED 10/30/2019
	Francis A Guidry Investigator (Biotechnology) Signed By: Francis A. Guidry -S Date Signed: 10-30-2019 12:14:37 X	

**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 10/22/2019-10/30/2019*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Cody Boatman, COO		FBI NUMBER 3014982757
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 Prescription Drug Manufacturer OUTSOURCING FACILITY	

OBSERVATION 2

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, a) you compound a drug product that is 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:

- **Testosterone Pellets** in 12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 87.5 mg, 100 mg, and 200 mg strengths.

OBSERVATION 3

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

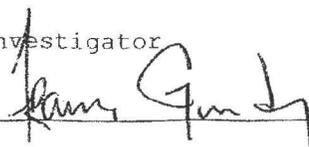
Specifically, you are not monitoring the environmental conditions for each batch of product you manufacture.

Examples of compounded drug products lots that were ^{NOT AC} environmentally monitored during production:

- BR, Lot 176, and BR, Lot 178

***DATES OF INSPECTION**

10/22/2019(Tue), 10/23/2019(Wed), 10/24/2019(Thu), 10/25/2019(Fri), 10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Francis A Guidry, Investigator (Biotechnology)		DATE ISSUED 10/30/2019
			