DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	10/28/2024-11/8/2024*
	FEI NUMBER 3010348724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher S. Musser, RPh, Vice President Operations, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
F.H. Investments Inc.	7004 Champion Blvd Ste 100
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35242-6500	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

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

Specifically,

You failed to conduct complaint investigations for the following customer reported product quality issues regarding your sterile compounded drug pellets:

- Complaint, CC024-002, dated 09/13/24; Pellets did not fit into trocar kits used for subdermal placement: Testosterone 37.5 mg, Lot (b)(4); Testosterone 25 mg, Lot (b)(4); Testosterone 87.5 mg, Lot (b)(4)
- Complaint, CC024-04, dated 09/13/24; Multiple units received as only powder, no pellet: Estradiol 6 mg and 10 mg (no lot information)
- Complaint, CC024-07, dated 10/03/24; Pellet stuck in vial container: Estradiol 6 mg, Lot (b)(4)
- Complaint, CC024-09, dated 10/03/24; Pellet stuck in vial container and crumbled in tweezers: Estradiol 12.5 mg, Lot (b)(4)
- Complaint CC24-012, dated 10/21/24; Variable pellet color and shape; Testosterone 200 mg, Lot (b)(4)
- Complaint CC24-013, dated 10/21/224; Pellets did not fit into trocar kits used for subdermal placement: Testosterone 200 mg (not lot provided)
- Complaint, CC024-14, dated 10/24/24; Pellet disintegrated upon opening vial container: Estradiol 6 mg, Lot (b)(4); Estradiol 12.5 mg, Lot (b)(4)

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	Jolanna A Norton, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 11-08-2024 12:48:18	11/8/2024

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OBSERVATION 2

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 conduct dissolution testing as part of your finished product specification requirements prior to batch release, and therefore is unable to ensure subdermal implant pellets do not dissolve immediately, remain integral (do not crumble or break into pieces), and release active pharmaceutical ingredients at a rate that is reproducible. Dissolution testing has not been performed for the following sterile compounded drug products produced at your facility:

(b)(4)

Estradiol 6 mg
Estradiol 10 mg
Estradiol 12.5 mg
Estradiol 15 mg
Estradiol 18 mg
Estradiol 20 mg
Estradiol 22 mg
Estradiol 25 mg
Estradiol 37.5 mg
Testosterone 12.5 mg
Testosterone 18 mg
Testosterone 25 mg
Testosterone 37.5 mg
Testosterone 50 mg
Testosterone 62.5 mg

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(b)(4) Testosterone 87.5 mg
Testosterone 100 mg
Testosterone 200 mg
Testosterone 303 mg
Testosterone/Anastrozole 60 mg/ 4 mg
Testosterone/Anastrozole 75 mg / 4 mg
Testosterone/Anastrozole 100 mg / 4 mg
Testosterone/Anastrozole 200 mg / 10 mg
Testosterone/Triamcinolone Acetonide 87.5 mg / 17.5 mcg
Testosterone/Triamcinolone Acetonide 100 mg / 20 mcg
Testosterone/Triamcinolone Acetonide 200 mg / 40 mcg

OBSERVATION 3

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,

Your equipment cleaning process has not been validated to ensure there is no cross-contamination between hazardous and highly-potent hormone active pharmaceutical ingredients (APIs), including, testosterone and estradiol. Your firm produces multiple compounded hormone drug products using non-dedicated equipment, including pellet presses that have multiple product contact parts, (b)(4) control hoods, analytical balances, and calipers. Additionally, a non-dedicated vacuum cleaner is used to remove powder drug substance from production equipment and surfaces. For example,

A) On October 29, 2024, your operator performed inadequate cleaning of product contact equipment and adjacent areas following production of Testosterone 100 mg pellets, Lot (b)(4), Exp 08/2025. A white residue was observed on the surfaces of the pellet press and the (b)(4) containment hood after post-production cleaning. Your supervising production pharmacist identified the white

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residue as testosterone drug powder mix. White residue was observed on inner and outer surfaces of the (b)(4) cabinet between ISO 8 Production Room (b)(4) and gowning Ante Room (b)(4) Additionally white residue was also observed on surfaces of containers holding in-process pellets placed into the (b)(4) cabinet for transfer to non-classified storage area.

B) Your firm lacks adequate controls to prevent cross-contamination of non-dedicated production equipment and areas from the non-dedicated vacuum cleaner used to remove loose hazardous and highly potent drug substance powders from equipment surfaces, including pellet presses and (b)(4) containment hoods, in ISO 8 Production Rooms (b)(4) and (b)(4) Cleaning of the vacuum is not documented on cleaning forms, and the vacuum is not sampled/tested for drug residue following changeover cleaning. There is no documented maintenance of the vacuum's HEPA exhaust filter since December 2018. On October 29, 2024, during cleaning of Room (b)(4) the operator was observed using the vacuum to clean powdered drug product from the pellet press following production of Testosterone 100 mg pellets, Lot (b)(4), Exp 08/2025. After cleaning ended, a white powder residue was observed inside and outside the vacuum nozzle. Written procedure, SOP NSC 04 Cleaning and Restocking – ISO 8 Rooms does not instruct cleaning the vacuum. Cleaning form, NSC 04, does not document cleaning of vacuum cleaner.

OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically,

Your firm lacks adequate controls to prevent cross-contamination within ISO 8 Anterooms. Anterooms

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are used for personnel gowning and storage of gowning materials, personal protection equipment (PPE), and cleaning equipment. Operators enter the anteroom in outside clothes and open new gowning within the same space that is exposed to hazardous powder drug product from gowning worn during production. For example:

A) On 10/29/2024, your production operator, wearing gowning coveralls and respirator PPE, was observed exiting Production Room (b)(4) to move through and handle items in Anterooms (b)(4) and (b)(4) following production of compounded hazardous drug product, Testosterone 100 mg pellets, Lot (b)(4), Exp. 08/2025. The operator's gowning and PPE had been exposed to hazardous powder drug product during production.

B) On 10/29/24, disposable gowning was observed hanging in ISO 8 Anteroom (b)(4) during operator breaks. The gowning had been worn during earlier production operations in Production Room (b)(4) involving (b)(4) pellet placement into vial containers for hazardous compounded drug product, Testosterone 50 mg, Lot (b)(4), Exp 07/2025.

OBSERVATION 5

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

Specifically,

Your firm relies on (b) (4) reported Certificates of (b) (4) as sterility assurance for batch release of your compounded hormone drug products purported to be sterile. You firm lacks (b)(4) (b) (4) sterility testing results in 2024 to validate sterility assurance per (b) (4) reported on certificates of (b) (4).

***DATES OF INSPECTION**

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10/28/2024(Mon), 10/29/2024(Tue), 10/30/2024(Wed), 10/31/2024(Thu), 11/01/2024(Fri), 11/04/2024(Mon), 11/07/2024(Thu), 11/08/2024(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."