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 CompoundingInspections@fda.hhs.gov	12/05/2025-12/19/2025
	FEI NUMBER 3038253438

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

FIRM NAME	STREET ADDRESS
F.H.Investments,Inc.(dba Asteria Health)	432 Industrial Ln
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35211-4465	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

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm has been manufacturing and distributing implantable hormone pellets since May 2025 without conducting process validation. Your firm has not performed Performance Qualification (PQ) on any equipment used for drug production nor has your firm executed Process Validation Qualification (PPQ) for any of your drug products. Your justification includes legacy data from commercial batches produced and distributed and claims of no changes to equipment, formulation, and materials.

However, your firm has made changes to your manufacturing process by, for example:

- Adding new equipment (i.e., metal detectors, weight sorters) that were not previously apart of your manufacturing process
- Changing drug formulation in the master batch record. For example, changing the ratio of active pharmaceutical ingredient and excipient for Testosterone/Anastrozole pellet products.
- Changing the visual inspection and sampling process

Your firm was made aware of lack of process validation and inadequate process validation as it was cited by a third-party audit between September 30, 2025, and October 3, 2025. Your firm documented this as opportunities for improvement.

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	Bei Y. He, Investigator	BEI Y. HE -S Digitally signed by BEI Y. HE -S Date: 2025.12.19 13:52:07 -06'00'	12/19/2025

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Your manufacturing processes are not in a state of control, these include, but are not limited to:

A. **Ongoing metal and foreign material contamination** from inadequately qualified equipment (pellet presses, microcappers, metal detector) and lack of process control and resulting in batch rejections, including:

Date	Deviation #	Type of Contamination
05/27/2025	DV25-035	**Metallic shaving** generated from **microcappers** (b) (4) , leading to one rejected batch- Testosterone 87.5mg pellet, Lot (b) (4) ((b) (4) **pellets rejected)**
06/27/2025, 07/01/2025	DV25-041	**Metallic shavings** generated from **pellet pressers** (b) (4) and (b) (4) leading to **two rejected batches** – Estradiol 25mg, Lot (b) (4) and Estradiol 15mg, lot (b) (4)
10/17/2025	DV25-070	**Metallic shavings** generated from **microcappers** (b) (4) and (b) (4) leading to one rejected batch- Estradiol 15mg pellet, Lot (b) (4)
10/24/2025	DV25-077	**Metallic shavings** generated from **pellet presser** (b) (4) leading to one rejected batch - Testosterone 100mg, Lot (b) (4) . Your firm rejected this batch during the inspection.
11/17/2025	DV25-079	**Translucent shavings** generated from **microcapper** (b) (4) , leading to one rejected batch – Testosterone 87.5mg, Lot (b) (4) . Your firm rejected this batch during the inspection.

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1. In late October 2025 as part of CAPA25-030, your firm implemented metal detectors in your process. However, your firm has since continued to have metallic contamination in your drug products. For, Testosterone/ Anastrozole 100mg/4mg, Lot 254000114, produced on (b) (4), it was observed to what appears to be metallic foreign material approximately <0.1mm in "(b) (4)(b) (4) WASTE." This waste material came from your pellet pressing operation. Even though this lot is under quarantine status, your firm has yet to determine the source of this contaminant (e.g., whether the contaminant was generated from material, pellet press, sieving, or others process).

2. Your firm has not properly qualified the following equipment for manufacturing, these include but are not limited to:

Manufacturing Function	Equipment	Asset
Pressing powders into pellets	(b) (4) Pellet Press	(b) (4) in room (b) (4) in room in room
Detect metal ((b) (4)) after pellet pressing	Metal Detector	in room in room in room
Vialing and capping pellets	Microcappers	(b) (4)

Your equipment qualification is inadequate as evidenced by:

a) **Incomplete equipment qualification** having performed only Installation and Operational Qualification (IQ/OQ) **without required Performance Qualification (PQ)** for pellet presses, microcappers, and metal detectors.

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b) **Inadequate Operational Qualification** for pellet presses where you failed to ensure the vacuum pressure gauge was calibrated during OQ and before manufacturing use in May 2025. Currently, you lack certification to ensure pressure gauge accuracy, which is critical for adequate product flow and the shaping of the final product in the pellet press.

Additionally, per CC25-042, you moved pellet press (b) (4) from room (b) (4) to room (b) (4) and moved pellet press (b) (4) from room (b) (4) to room (b) (4). **Your firm did not requalify pellet presses after their relocation**. Your firm determined "there was no impact to validated state" because "the equipment does not require calibration." Your assessment was incorrect as you were unaware until December 15, 2025, that your vacuum pressure gauge required calibration.

c) **Inadequate performance qualification** for microcapper. During the performance qualification of one of your microcappers on December 12, 2025, you did not use any of the products you manufactured to qualify this equipment. Instead, you performed this qualification with empty vials without any product. This is not a represent of your current manufacturing process where operators (b) (4) load each pellet into the vial and cap the vial using the microcapper.

B. Multiple Potency and Process Failures leading to rejected batches. The following examples include but are not limited to:

Date	Report	Product (lot) / Release Status	Issue/Root-Cause as Determined by the Firm
06/30/2025	DV25-042;	Testosterone/Anastrozole 200mg/10mg, Lot (b) (4), **Rejected as "pellets would not hold together"**	**Error in the master batch record** leading to incorrect powder formulation

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06/30/2025	DV25-046; OOS25-002;	Testosterone/Anastrozole 60mg/4mg, Lot (b) (4), **Rejected for out-of-specification potency release testing.** Results: **89.5%; 84.0%; 88.2%** Specification: (b) (4)	**Error in the master batch record** leading to incorrect powder formulation
08/19/2025	OOS25-003; DV25-052; CC25-041;	Estradiol 6mg, Lot (b) (4) **Rejected for out-of-specification for potency release testing.** Potency Result: **81.6%** Specification: (b) (4)	(b) (4) **process – not controlled and lack of procedure to standarize this process.**
09/04/2025	OOS25-004	Estradiol 6mg Lot (b) (4). **Could not perform potency testing due to broken pellet.**	**Broken Pellet-** "Pellet can become damaged or broken during shipping process, sterilization process, or handling process"

C. **Lack of sterilization validation** – your firm relies on (b) (4) **batches** (e.g., (b) (4)) created by (b) (4) to validate (b) (4) sterilization processes. This non-representative approach does not represent your actual production processes, individual product formulations, or final products distributed to patients, which may have different sterilization resistance, bioburden levels, density, pellet size, and processing steps. Currently, your firm has not executed any sterilization validation for the products you manufactured at this facility.

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D. Absence of dissolution and hardness/friability testing for process performance validation. The lack of testing fails to ensure consistent drug release, prevent dose dumping, and control batch variability. In addition, your firm has not validated all your dissolution testing methods and has not established any hardness/friability testing.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

Your non-representative dose audits does not provide assurance that commercial hormone pellet products achieve sterility or maintain quality after sterilization., for the following hormone pellets that were manufactured and released at this facility.

Drug Product	Strengths	Length	Pellets Produced / Batch*	Number of Released Batches	BUD*
Testosterone	12.5mg, 18mg, 25mg, 37.5mg, 50mg, 62.5mg, 87.5mg, 100mg, 200mg, 303mg	3.2mm	(b) (4)	(b) (4)	365 days
Estradiol	6mg, 10mg, 12.5mg, 15mg, 18mg, 20mg, 22mg, 25mg, 37.5mg	3.2mm	(b) (4)	(b) (4)	

Testosterone/ Triamcinolone Acetonide	87.5mg/17.5mcg, 100mg/20mcg, 200mg/40mcg	3.2mm/ 4.3mm	(b) (4)	(b) (4)	
Testosterone/ Anastrozole	60mg/4mg, 75mg/4mg, 100mg/4mg, 200mg/10mg	3.2mm/ 4.5mm	(b) (4)	(b) (4)	

*Data derived from 001.2 Drug production log for May 2025 to December 2025.
**Expiration date is either 365 days (b) (4) or the (b) (4)

Your firm relies on sterility data from a non-representative batch (e.g., (b) (4) batch size (b) (4) vials) created by (b) (4) ((b) (4)) (b) (4) for (b) (4) sterilization dose audits. This non-representative batch approach does not represent your actual production processes, individual product formulations, or final products distributed to patients, which may have different sterilization resistance, bioburden levels, density, and processing steps.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your quality unit has failed to ensure appropriate oversight for changes to master batch records. For example, as part of PRO25-035, your firm updated the powder formulation for Testosterone Anastrozole products. However, your quality unit failed to appropriately review and adjust the weight of (b) (4) accordingly, leading to incorrect formulation direction or pellet

weighing specifications issued for manufacturing the following, including but not limited to:

- Testosterone/Anastrozole 200mg/10mg, Lot (b) (4) – **REJECTED** due to "pellets would not hold together." Your investigation (DV25-042) determined that it was an error in the master batch record leading to formulation failure.

- Testosterone/Anastrozole 60mg/4mg, Lot (b) (4) **-REJECTED** due to failed in-process potency testing. Your investigation (DV25-046) determined that it was an error in the master batch record leading to potency failure.

- Testosterone/ Anastrozole 75mg/4mg, Lot **254000107 -RELEASED** due to weight specifications passing despite the error in the master batch record.

B. Your quality unit has failed to establish an effective visual inspection program designed to qualify operators on identifying defects as evident by:

1. Absence of defect library system to train visual inspectors and the visual inspection process.

2. Absence of qualification test sets for qualifying visual inspection operators. Consequently, your firm cannot verify operators possess the necessary skills to identify defects in drug products.

3. Absence of procedure for identifying, evaluating, and incorporating new defect types into the defect library.

C. No documented rationale exists for a sampling size of (b) (4) vials when performing AQL, on batches for example ranging from (b) (4) units to (b) (4) units, after the 100% visual inspection of pellets. For example, but not limited to:

- Testosterone 200mg, Lot 251000180, EXP 09/19/2026 (QTY (b) (4)) **-RELEASED**
- Testosterone 200mg/ Triamcinolone Acetonide 40mcg, Lot 256000105, EXP 09/23/2026 (QTY (b) (4))- **RELEASE**
- Estradiol 10mg, Lot 253000162, EXP 09/12/2026 (QTY (b) (4)) – **RELEASED**

D. Your quality unit has failed to establish an effective CAPA program as evident by:

CAPA #	Issue	Opened Date	Due Date	CAPA Status	CAPA Duration
CAPA25-021	Stability study	06/26/2025	(b) (4)	Open	**>6 months**
CAPA25-035	Process validation	09/30/2025	(b) (4)	Open	**>6 months**
CAPA25-039	Hold times for in-process powder and pellets	10/02/2025	(b) (4)	Open	**>8 months**

Your quality unit characterized these critical CAPAs as merely "gaps" in the process for improvement, minimizing fundamental cGMP deficiencies. Despite these outstanding CAPAs for process validation, stability testing, hold time testing for in-process materials and as of December 15, 2025, your firm continues to manufacture and release hormone pellets.

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E. Your quality unit has failed to establish procedures that:

1. Define user roles and access controls for HPLC systems and frequency for reviewing user roles and permissions.

2. Govern data review procedures for data generated from the metal detector. For example, your metal detector logs pellet rejects. You firm does not review nor capture these data to support batch release decision and to investigate contamination events.

OBSERVATION 4

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically,

A. Your quality unit failed to investigate the following events:

- Rejected Estradiol 6mg, Lot (b) (4) on July 10, 2025, for "issues experienced with powder during pressing" without opening any investigation.

- No investigation was conducted for a confirmed laboratory out-of-specification investigation (OOS25-004, failed potency testing due to broken pellet).

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- Two separate contamination events, occurring over different days, by combing into one deviation report (DV25-041). This process of combing deviation events is not an established process in your deviation SOP and undermines your ability to investigate contamination events.

B. Inadequate investigation of recurring metallic and foreign contamination events:

Date	Deviation /CAPA	Contamination Event	Root Cause(s) as determined by the firm
05/27/2025	DV25-035/ CAPA25-016	Metallic shavings from microcapper (b) (4) pellets rejected	Inadequate maintenance procedure
06/27/2025, 07/01/2025	DV25-041/ CAPA25-024	Metal shavings from pellet presses (b) (4) and (b) (4) , (b) (4) batches rejected	Insufficient operator training, component wear
10/17/2025	DV25-070/ CAPA25-041	Metallic shavings from microcappers (b) (4) and (b) (4) , batch rejected	Internal wear of components
10/24/2025	DV25-077/ N/A	Metallic materials from pellet press (b) (4) , batch rejected	Internal wear of components
11/17/2025	DV25-079/ CAPA25-048	Translucent shavings from microcapper (b) (4) , batch rejected	Wear in (b) (4) wheels

Your firm has not adequately conducted investigations for these contamination events as evident by:

1. **Continued contamination**, metallic contaminant approximately <0.1mm in "(b) (4)(b) (4) WASTE" for Testosterone/Anastrozole 100mg/4mg, Lot 254000114 manufactured on (b) (4) , from pellet pressing operations using (b) (4) in room (b) (4).

2. **Limited investigation scope:** your firm has failed to analyze contamination types or sources, collect photographic evidence, or characterize contaminant properties, instead treating contamination as waste without investigation, despite repeat contamination occurrences over six months and operators identifying contaminants.

OBSERVATION 5

Aseptic processing areas are deficient in that wall are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

On December 4, 2025, the FDA investigator observed that the side (b) (4) containment shield of Pellet Press (b) (4) is cracked, making the area difficult to decontaminate and clean. Highly potent and hazardous hormone pellets are manufactured inside this containment system.

For example:

- Testosterone 200mg, Lot 251000180, EXP 09/19/2026 (QTY (b) (4)) **-RELEASED**
- Estradiol 10mg, Lot 253000132, EXP 06/16/2026 (QTY (b) (4)) **-RELEASED**
- Estradiol 12.5mg, Lot 253000130, EXP 06/16/2026 (QTY (b) (4)) **-RELEASED**

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OBSERVATION 6

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's current release testing program involving weight, pellet length, endotoxin, dosimetry, and potency testing is inadequate to ensure the quality of solid dosage forms intended for (b) (4) . Your firm has failed to establish appropriate release testing specifications for implantable hormone pellets, including:

- **Absence of dissolution testing** for batch release to ensure consistent drug release and prevent dose dumping, control batch variability, and quality control for implantable products.
- **Absence of hardness/friability testing** for batch release to ensure pellets maintain structural integrity during the intended multi-month implantation period.

Your firm has released more than (b)(4) batches covering over (b) (4) pellets to patients across (b)(4) states since May 2025 without adequate release testing, failing to ensure that hormone pellets meet appropriate standards of identity, strength, quality, and purity before distribution to patients.

OBSERVATION 7

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.

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Specifically,

Your firm did not initiate stability studies until December 3, 2025, for implantable pellet products manufactured at this facility. Stability studies should have been conducted before releasing products to the market to support beyond use dating/expiration dating on your product labels. In the absence of stability data generated from batches manufactured at this facility, you assigned an expiry of 365 days for all batches based on legacy data from another facility. Your justification that you have the same equipment, formulation, materials are inappropriate as:

- Environmental conditions including microbial floras may differ
- Material and people flow during manufacturing may differ
- Facility layout, construction, and HVAC systems may differ
- Manufacturing process validation may differ

Legacy data from different facilities cannot substitute for facility-specific stability data required to support expiration dating and batch release.

OBSERVATION 8

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

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Your laboratory manager reviews only printed chromatograms and audit trail data without reviewing raw electronic data. This process does not ensure the accuracy and reliability of analytical results used for batch release decisions. The lack of review of raw electronic data generated by analytical instruments limits the ability to detect data integrity issues and system malfunctions that could affect batch release decisions.

OBSERVATION 9

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

During this inspection, FDA investigators observed multiple data governance and document control deficiencies affecting the reliability and integrity of data used for batch release decisions:

A. **Unrestricted analytical system access** where your lab manager logged into the (b) (4) chromatography system on December 4, 2025, without user login credentials and operated under "Admin" user profile with unrestricted access to audit trails, methods, and sequences deletions. Sequence reports since May 2025 show all potency testing for batch release was performed under "admin" accounts, compromising data integrity for critical quality decisions.

B. **Inadequate batch record and document control** where environmental monitoring, personnel monitoring, sampling, and visual inspection forms that support batch release decisions are

accessible for unlimited printing by non-QC personnel without reconciliation controls such as date/time stamps, page number, issuance tracking.

C. **Uncontrolled equipment documentation** where equipment maintenance, cleaning, and use logbooks are not bound or controlled, including HPLC maintenance logs, calibration records, and cleaning documentation, allowing potential alteration or loss of critical data supporting product quality decisions.

These data integrity deficiencies compromise the reliability of analytical and manufacturing data generated since facility operations began in May 2025, affecting the assurance that products meet specifications and can be distributed for patient use

OBSERVATION 10

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, and processing.

Specifically,

Your firm implemented metal detection testing approximately in October 2025 for each pellet batch as a corrective measure to identify metal shavings and particles that had been found in previous batches beginning in June 2025. However, the results of these metal detection tests are not documented. Additionally, when metal contamination is identified, the contaminated pellets and metal fragments are discarded as waste. The lack of metal detection documentation in batch records may impair the quality unit's capacity to make well-informed batch release determinations.

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*DATES OF INSPECTION

12/05/2025 (Mon), 12/08/2025(Mon), 12/09/2025(Tue), 12/10/2025(Wed), 12/12/2025(Fri), 12/15/2025(Mon), 12/17/2025(Wed), 12/19/2025(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."