DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/12/2018-07/10/2018
	FEI NUMBER 3010348724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William E. Fixler, Co-Owner & Pharmacist in Charge	
FIRM NAME FH Investments Inc. dba Asteria Health	STREET ADDRESS 7004 Champion Blvd, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35242	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) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically, during (b) (4) (b) (4) sterilization validation,

a. The bioburden and sterility method validation and suitability testing used for dose verification testing were not performed using testosterone and estradiol pellets made by your firm.
b. The sterility and bioburden testing methods do not evaluate the entirety of each implantable pellet, only the external surfaces.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Specifically, sterility testing of hormone pellets during (b) (4) only provides information for the exterior surfaces of the implantable pellets. There is no evaluation of the entire pellet.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	07/10/2018

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OBSERVATION 3

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

Specifically, the equipment cleaning process has not been validated to ensure there is no cross-contamination between the hormone active pharmaceutical ingredients (APIs), testosterone and estradiol. The (b) (4) Pellet Press, (b) (4), is used for both API products and poses the highest risk for cross-contamination due to non-dedicated product contact parts. Other equipment used with both APIs include (b) (4) hoods, analytical balances, and calipers.

OBSERVATION 4

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. Specifically, the assessment of the investigation into the assay failure of an Estradiol 6 mg Pellet, Lot 04252017@3, at the (b) (4) time-point lacks evidence to support invalidation of the out-of-specification (OOS) result.

OBSERVATION 5

Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

***DATES OF INSPECTION:**

06/12/2018 (Tue), 06/13/2018 (Wed), 06/14/2018 (Thu), 06/15/2018 (Fri), 06/18/2018 (Mon), 06/19/2018 (Tue), 06/20/2018 (Wed), 7/2/2018 (Mon), & 7/10/2018 (Tue)

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	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	07/10/2018