DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District Office - FDA 6th Ave and Kipling St. - Building #20 Denver, CO 80225 303-236-3000 Industry Information: www.fda.gov/oc/industry	01/09/2017-01/12/2017, 01/19/2017
	FEI NUMBER 3013159937

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Teri M. Rolan

FIRM NAME	STREET ADDRESS
In Your Atmosphere Holdings LLC	1676 Hospital Dr
CITY, STATE AND ZIP CODE Santa Fe, NM 87505-4754	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically, written procedures for cleaning do not always have descriptions in sufficient detail of methods, equipment and parameters (such as volume, contact time, and temperature of deactivating/sanitization agent) to ensure effective and reproducible cleaning results in order to prevent cross-contamination between drug products. For example:

A. SOP-2.40 (b) (4) Version 1.0, reads in part, "(b) (4)

B. SOP-2.20 (b) (4) Version 1.0, reads in part, "(b) (4)

C. SOP-2.110 (b) (4) Version 1.0, reads in part, "(b) (4)
And also states in part, "(b) (4)

Observation 2

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, in a system where highly active compound (e.g. progesterone, testosterone, or estradiol) drug manufacturing equipment is not product dedicated,

A. Equipment cleaning and sanitization operations have not been shown to be effective in removing unwanted product residues, cleaning agent residues, or other potential contaminants that could be introduced from equipment surfaces, utensils, and/or drying rags.

B. Instructions identified on the cleaning agent bottle of (b) (4) are not followed. Hold time instructions are not followed for the approximately (b) (4) used to clean equipment, utensils, and production

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operating surfaces. You do not monitor or record hold time operations for your cleaning operations that are all (b) (4)

Observation 3

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

Specifically, your firm's procedures do not define the roles and responsibility of a quality control unit. There are no written procedures detailing the authorities of the quality control unit to include approval and rejection of procedures, release of drug products, and maintenance of specifications for ingredient and finished product identity, strength, quality and purity. Additionally, procedures do not describe responsibilities of the quality control unit as it pertains to complaint investigations, root cause analysis, and corrective/preventative actions plans. The firm has not assigned the role of quality unit manager to a specific individual.

Furthermore, you stated that in approximately the past 30 days, the firm has implemented a (b) (4) (b) (4) Prior to the establishment of the (b) (4) program, (b) (4) There is no documentation to support that a (b) (4) program has been implemented.

Observation 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug product containers, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your firm does not conduct any tests to determine identity, strength, purity, and composition for at least (b) (4) of the approximately (b) (4) unique formulations that were produced between 2015 and 2017. Contract testing of your firm's products is limited to (b) (4) potency analysis of (b) (4) estradiol cream, (b) (4) testosterone cream, (b) (4) progesterone cream, and (b) (4) DHEA cream.

B. Since 10/10/2016, your firm has released at least (b) (4) prescriptions without performing testing on any incoming components including bulk substances and containers and closures.

C. Your firm has failed to perform qualification of raw material suppliers. The (b) (4) in lieu of testing. Zero identity, strength, potency, or purity testing is performed. Your firm has failed to identify the manufacturer of any raw materials.

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Observation 5
There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically,
A. Equipment qualifications have not been assessed for the following major manufacturing equipment used by pharmacists and technicians in the production of drug products: (b) (4)

B. Process validation has not been performed in support of the approximately (b) (4) unique formulations that you have identified on your list of products manufactured between 2015 and 2017.

Observation 6
Your firm failed to routinely calibrate, inspect or check according to a written program designed to assure proper performance and to maintain adequate written records of calibration checks and inspection of automatic, mechanical or electronic equipment. Calibrations have not been performed and documented for (b) (4) (b) (4) used in the "compounding pharmacy suite", refrigerator, and freezer. (b) (4) thermometers are used in the refrigerator and freezer that hold temperature sensitive materials such as dimethylaminoethanol.

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. Specifically, your firm has not collected any data in support of beyond use dates (BUD) applied to drug products processed on site. For example,
A. Current BUD for (b) (4) Estradiol 1mg/0.1mL cream is 180 days. This value is identified in the PK Logged Formula Worksheet Rx (b) (6) as "per (b) (4) ". Your firm has not executed stability studies in support of the 180 day BUD.
B. Current BUD for (b) (4) Women's Testosterone 1mg/0.1mL cream is 180 days. This value is identified in the PK Logged Formula Worksheet Rx (b) (6) as "per (b) (4) ". Your firm has not executed stability studies in support of the 180 day BUD.
C. Current BUD for (b) (4) Progesterone 20mg/0.1mL cream is 180 days. This value is identified in the PK Logged Formula Worksheet Rx (b) (6) is "per (b) (4) ". Your firm has not executed stability studies in support of the 180 day BUD.

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Observation 8

Employees are not given training in current good manufacturing practices (GMP). Specifically, your firm has not performed and documented GMP training. Of the (b) (4) pharmacists and (b) (4) technicians working on site, none have participated in GMP training since the establishment of the business in 2014.

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