Deriver District OFFICE ADDRESS       DATE(5) OF NAMECINA         Deriver District Office - FDA       DATE(5) OF NAMECINA         Office ADDRESS       DATE(5) OF NAMECINA         303-325-3000       DERIVER, CONSTRUCT ON NOM REPORT BISSUED         TO:       Ms. Terl M. Rolan         FIRM NAME       STREET ADDRESS         Industry Information: www.fdx.gov/oc/industry       3013159937         NAME ADD TITE OF ROWDOWL, TO WHOM REPORT BISSUED       TO:         TO:       Ms. Terl M. Rolan         FIRM NAME       STREET ADDRESS         IN Your Atmosphere Holdings LLC       1676 Hospital Dr         TYR WITA ROS DO NOT REPORT BISSUED       TO: Ms. Terl M. ROBER         TO:       MS. Terl M. Rolan         THE DO DOWN REPORT FIGHT REPORT DEPORT       Producer of Non-Sterile Drug Products         Strate To, NM SERSYNTONS, ANGE BY THE FDA REPRESENTATINGS DARRON THE INSPECTION OF YOUR FACUTY. THEY ARE INSPECTION         OBSERVATIONS, AND DO NOT REPERSIVE OFFIRMMATICAL COMPARIAGENERY NAME AND ADDRESS ABOVE.         Observation 1       Writen 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, writen procedures for cleaning to 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 effecti		FO	OD AND DRUG ADMINISTRATION	
6th Ave and Kipling 81.0       Under 2012 Strate Stra			DA	TE(S) OF INSPECTION
Denver, CC 80225 301-236-3000 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF MONDULA. YO WHOM REPORT IS ISSUED TO: MS. TET M. Rolan FREMAME In Your Atmosphere Holdings LLC In Your Atmosphere In Your Atmosphere Setter Holding In Her Pool Representation of Non-Sterile Drug Products 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-containination between drug products. For example: A. SOP-2.20 (b) (4) Version 1.0, reads in part, "(b) (4) And also states in part, "(b) (c) A. Equipment cleaning and sanitization operations	and the second se			/09/2017-01/12/2017, 01/19/2017
Industry Information: www.fda.gov/oc/industry       3013159937         Your Atmosphere Holdings LLC       1676 Hospital Dr         Try Corr Atmosphere Holdings LLC       1676 Hospital Dr         Try Strate Aco Procee       Producer of Non-Sterile Drug Products         Segment Tool Not Try Enversity of Drawn The Respective Corr Cours Acount Read Non X and Conservations, and Do Not Respective Or Conservation Read Non X and Conservations, and Do Not Respective Provide Strate	Denver, CO 8			NUMBER
NAME AND THE OF HONDOUL TO WHOM REPORT IS ISSUED         TO: Ms. Terl M. Rolan         FRM NAME         In Your Atmosphere Holdings LLC         ITY FAR AND 2P CODE         Strike AND 2P CODE         Decision AND AND AND 2P CODE         Strike AND 2P CODE         This DOCUMENT USTS OBSERVATIONS MODE BY THE FDA STRIBUSTION OF YOUR FRAM ON ONE STORE TO AN OBSERVATION OF YOUR FRAM ON ONE STORE STATUTE (STORE AND ADDRESS ABOVE.         VOLHAVE ANY OWERTON OF YOUR FRAM ON (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 and reproducible cleaning to always have descriptions in sufficient detail of methods, equipment and parameters (such as volume, contact time, and temperature of deactivating/sanitization agent, to ensu		303-236-3000		013159937
PRIMARE       STREET ADDRESS         In Your Atmosphere Holdings LLC       1676 Hospital Dr         TY, STATE AROP CODE       Product of Non-Sterile Drug Products         The SockWard Stream Stre				
In Your Atmosphere Holdings LLC       1676 Hospital Dr         DTY, BTATE AND 2P CODE       YPE OF ESTABLISHMENT INSPECTED         Santa Fe, NM 87505-4754       Producer of Non-Sterile Drug Products         Descent Distribution Construction Construction Drug Status       Producer of Non-Sterile Drug Products         Descent Distribution Construction Drug Status       Producer of Non-Sterile Drug Products         Descent Distribution Construction Drug Status       Producer of Non-Sterile Drug Products         Descent Distribution Construction Drug Status       Producer of Non-Sterile Drug Products         Descent Distribution Construction Drug Status       Producer of Non-Sterile Drug Products         Descent Distribution Construction Distribution Dis	TO: Ms. Teri	M. Rolan		
DTY, BTATE AND 2/P CODE       TYPE OF ESTABLISHMENT INSPECTED         Small Fe, NM 87305-4754       Producer of Non-Sterile Drug Products         THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATION THE INSPECTION OF YOUR FACLITY. THEY ARE INSPECTION OF YOUR FACLITY. THEY ARE INSPECTION OF YOUR STANDARD PROVIDED STATUSTS, ON THE INSPECTION OF YOUR FACLITY. THEY ARE INSPECTION OF YOUR FIRM (0, 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 to not always have descriptions in sufficient detail of methods, equipment and parameter: (such as yolume, contact time, and temperature of deactivating/sanitization agent) to ensure effective and reproducible cleaning results in order to prevent cross-contamination between drug product. For example: A. SOP-2.20 (b) (4)         Version 1.0, reads in part, "(b) (4)       Version 1.0, reads in part, "(b) (4)         B. SOP-2.20 (b) (4)       Version 1.0, reads 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 add sanititzation operations have not been shown to be	FIRM NAME		STREET ADDRESS	Caral and a second
Santa Fe, NM 87505-4754       Producer of Non-Sterile Drug Products         Inte Document Lists deservations much set the row Representation and provementations of the row much memory on a row of the row much memory of the row of the row much memory of the row much memory of the row of the	In Your Atmo	osphere Holdings LLC	1676 Hospital Dr	
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(s) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONADES ADDRESS ADDRESS AND OS AND REPRESENTATIVE(s) DURING THE INSPECTION OF COMPLANCE BY YOUR HAVE AN OBJECTION REGARDING YOUR COMPLANCE BY YOUR HAVE AN OBJECTION REGARDING YOUR COMPLANCE BY YOUR HAVE AN OBJECTION REGARDING YOUR COMPLANCE BY YOUR HAVE AN OBJECTION FOR AND THE INSPECTION OF SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS TO AN OBJECTION FOR AND THE ADDRESS ADDRE	CITY, STATE AND	ZIP CODE	TYPE OF ESTABLISHMENT INSI	ECTED
Deservation 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.         Observation 2 Equipment cleaning and sanitization operations have not been shown to be effective in removing unwanted product. Specifically, in a system where highly active compound (e.g. progesterone, testosterone, or estradiol) drug manufacturing equipment is not product surfaces, itensils, and/or drying rags.         B. Instructions identified on the cleaning agent bottle of (b) (4)       Version shown to be effective in removing unwanted product. Specifically, in a system where highly are not followed for the clean product. Specifically, in a system where highly active compound (e.g. progesterone, testosterone, or estradiol) drug manufacturing equipment is not product and the product for the approximate bottle of (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 and to followed for the approximately (b) (4)	Santa Fe, NM	87505-4754	Producer of Non-Sterile I	Drug Products
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 equipmer surfaces, utensils, and/or drying rags. B. Instructions identified on the cleaning agent bottle of (b) (4) are not followed. Hold time instructions ar not followed for the approximately (b) (4) used to clean equipment, utensils, and production SEE BENELOYEE(S) SIGNATURE CATE ISSUED Zachary A. Bogorad, Investigator 01/19/2017	Observation Written pro- utensils, use procedures (such as vol reproducible	n 1 cedures are not established and foll ed in the manufacture, processing, p for cleaning do not always have de lume, contact time, and temperature e cleaning results in order to preven	packing or holding of a drug prod scriptions in sufficient detail of n e of deactivating/sanitization agen nt cross-contamination between d	uct. Specifically, written nethods, equipment and parameters nt) to ensure effective and rug products. For example:
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 equipmer surfaces, utensils, and/or drying rags. B. Instructions identified on the cleaning agent bottle of (b) (4) are not followed. Hold time instructions ar not followed for the approximately (b) (4) used to clean equipment, utensils, and production $\frac{EMPLOYEE(S) NAME AND TITLE (Print or Type)}{2achary A. Bogorad, Investigator}$		10 (b) (4) Version 1.0, read	ls in part, "(b) (4)	
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	Equipment alter the saft active comp dedicated, A. Equipme product resi surfaces, uto B. Instruction not followed	and utensils are not cleaned and sate bety, identity, strength, quality or pu- bound (e.g. progesterone, testostero ent cleaning and sanitization operat idues, cleaning agent residues, or o ensils, and/or drying rags. ons identified on the cleaning agen d for the approximately (b) (4)	arity of the drug product. Specific one, or estradiol) drug manufactur ions have not been shown to be e ther potential contaminants that c t bottle of (b) (4) are not f used to clean equipme	ally, in a system where highly ing equipment is not product ffective in removing unwanted ould be introduced from equipmen ollowed. Hold time instructions are nt, utensils, and production

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DISTRICT OFFICE ADDRESS AND PHONE NUMB	ier .	DATE(S) OF INSPECTION
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6th Ave and Kipling St Building #20 Denver, CO 80225		
303-236-3000		FEI NUMBER
Industry Information: www.fda.gov/oc/ind		3013159937
AME AND TITLE OF INDIVIDUAL TO WHOM REP	PORT IS ISSUED	
ro: Ms. Teri M. Rolan	and the second se	
FIRM NAME	STREET ADDRES	s
In Your Atmosphere Holdings LLC	1676 Hospita	
TTY, STATE AND ZIP CODE		LISHMENT INSPECTED
Santa Fe, NM 87505-4754	Producer of N	Non-Sterile Drug Products
procedures, release of drug produ- dentity, strength, quality and puri- control unit as it pertains to comp plans. The firm has not assigned t	cts, and maintenance of specification ity. Additionally, procedures do not laint investigations, root cause analy the role of quality unit manager to a proximately the past 30 days, the fir Prior to the	
implemented.		
Observation 4		
standards, sampling plans, and tes	st procedures designed to assure that form to appropriate standards of iden y tests to determine identity, strengt	sound and appropriate specifications, t drug product containers, in-process ntity, strength, quality and purity.
Specifically, A. Your firm does not conduct any the approximately <sup>(b) (4)</sup> unique form firm's products is limited to (b) (4 <sup>(b) (4)</sup> testosterone cream, <sup>(b) (4)</sup> proge B. Since 10/10/2016, your firm ha	b) potency analysis of <sup>(b)</sup> <sup>(4)</sup> esterone cream, and <sup>(b) (4)</sup> DHEA crea as released at least <sup>(b) (4)</sup> prescription	ns without performing testing on any
Specifically, A. Your firm does not conduct an the approximately <sup>(b) (4)</sup> unique form firm's products is limited to (b) (4 <sup>b) (4)</sup> testosterone cream, <sup>(b) (4)</sup> proge B. Since 10/10/2016, your firm has incoming components including b	b) potency analysis of <sup>(D)</sup> <sup>(4)</sup> esterone cream, and <sup>(b) (4)</sup> DHEA crea as released at least <sup>(b) (4)</sup> prescription bulk substances and containers and c	een 2015 and 2017. Contract testing of your estradiol cream am. as without performing testing on any closures.
Specifically, A. Your firm does not conduct an the approximately <sup>(b) (4)</sup> unique form firm's products is limited to (b) (4 <sup>b) (4)</sup> testosterone cream, <sup>(b) (4)</sup> proge B. Since 10/10/2016, your firm has incoming components including b C. Your firm has failed to perform in	b) potency analysis of <sup>(D)</sup> <sup>(4)</sup> esterone cream, and <sup>(b) (4)</sup> DHEA crea as released at least <sup>(b) (4)</sup> prescription bulk substances and containers and c in qualification of raw material suppl	een 2015 and 2017. Contract testing of your estradiol cream am. as without performing testing on any closures. liers. The (b) (4) th, potency, or purity testing is performed.
Specifically, A. Your firm does not conduct an the approximately <sup>(b) (4)</sup> unique form firm's products is limited to (b) (4 <sup>b) (4)</sup> testosterone cream, <sup>(b) (4)</sup> proge B. Since 10/10/2016, your firm has fincoming components including b C. Your firm has failed to perform in Your firm has failed to identify th	b) potency analysis of <sup>(b)</sup> <sup>(4)</sup> esterone cream, and <sup>(b)</sup> <sup>(4)</sup> DHEA crea as released at least <sup>(b)</sup> <sup>(4)</sup> prescription bulk substances and containers and c in qualification of raw material suppl lieu of testing. Zero identity, strengt the manufacturer of any raw materials	een 2015 and 2017. Contract testing of your estradiol cream am. as without performing testing on any closures. liers. The (b) (4) th, potency, or purity testing is performed. s.
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Specifically, A. Your firm does not conduct an the approximately <sup>(b) (4)</sup> unique form firm's products is limited to (b) (4 <sup>b) (4)</sup> testosterone cream, <sup>(b) (4)</sup> proge B. Since 10/10/2016, your firm has fincoming components including b C. Your firm has failed to perform in Your firm has failed to identify th	b) potency analysis of <sup>(b)</sup> <sup>(4)</sup> esterone cream, and <sup>(b)</sup> <sup>(4)</sup> DHEA crea as released at least <sup>(b)</sup> <sup>(4)</sup> prescription bulk substances and containers and c in qualification of raw material suppl lieu of testing. Zero identity, strengt the manufacturer of any raw materials	een 2015 and 2017. Contract testing of your estradiol cream am. as without performing testing on any closures. liers. The (b) (4) th, potency, or purity testing is performed. S. AND TITLE (Print or Type) DATE ISSUED ad, Investigator 01/10/2017

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6th Ave and Kipling St Building #20			
Denver, CO 80225 303-236-3000		FEINUMBER	
Industry Information: www.fda.gov/oc/indust		3013159937	Sec. 1
NAME AND TITLE OF INDIVIDUAL TO WHOM REPOR	T IS ISSUED		
ro: Ms. Teri M. Rolan	STREET ADDRESS	the second second	And Section
In Your Atmosphere Holdings LLC	1676 Hospital		
TTY. STATE AND ZIP CODE			
Santa Fe, NM 87505-4754		n-Sterile Drug Products	
Observation 5 There are no written procedures for phe identity, strength, quality, and pu	irity they purport or are represented	to possess. Specifically,	
A. Equipment qualifications have no pharmacists and technicians in the p		najor manufacturing equipme (b) (4)	ent used by
pharmacists and technicians in the p	roduction of drug products.	(b) (4)	
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	FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
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TO: Ms. Teri M. Rolan		
FIRM NAME	STREET ADDRESS	
In Your Atmosphere Holdings LLC	1676 Hospital I	Dr
CITY, STATE AND ZIP CODE	TYPE OF ESTABLIS	SHMENT INSPECTED
Santa Fe, NM 87505-4754	Producer of No	on-Sterile Drug Products

## **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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SEE REVERSE OF THIS PAGE	Gaar Kocy	Zachary A. Bogorad, Investigator Nayan J. Patel, Investigator	01/19/2017
	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED