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Indust NAME AND TIT	ry Inform	nation: www.fda.gov/	oc/industry			
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observation action with	on, or have imp th the FDA rep	t represent a final Agency detern plemented, or plan to implement presentative(s) during the inspec of FDA at the phone number and	t, corrective action in re tion or submit this info	sponse to an obse	rvation, you may discuss	the objection o
DURING	AN INSPECTION	ON OF YOUR FIRM I OBSERVE	:D:			
OBSER	VATION 1					
Procedu	res designed	to prevent microbiological co	ontamination of drug	products purpor	ting to be sterile do no	t include
		lization process.		F	0	
	cally,	<sup>2</sup> (b) (4)	sterilization pro	cedures curre	ntly being perform	red for the
A.	Your firm (b) (4) st	's(b) (4) terilization of all sterile data for the <mark>(b) (4)</mark>			ently being perform . This includes lacl	
A.	Your firm (b) (4) st validation	terilization of all sterile data for the <mark>(b) (4)</mark>	drug products are	not validated	. This includes lacl	k of
А.	Your firm (b) (4) st validation Your phar	terilization of all sterile data for the (b) (4) macist stated he does no	drug products are t have a written c	not validated alibration pro	. This includes lacl	k of
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current production processes and conditions that represent the most stressful/challenging conditions and optimize detection of any microbiological contamination. For example, there is no media fill data for your current operation of filling over (b)(4) multidose glass vials (10 mL) for a prepared batch that uses (b) (4) glass vials, stoppers, caps that are sterilized in-house.

### **OBSERVATION 3**

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

- A. I could not verify the claimed classifications for these areas based on the inadequate certification documentation that was provided to me during this inspection. For example:
  - 1. No leak test was performed on the HEPA filters inside your Ante room, Gowning room, and Buffer room.
  - 2. Air flow measurements were not conducted under dynamic conditions.
  - 3. No dynamic airflow pattern studies (i.e., smoke studies) have been performed in the laminar flow hood inside your Buffer room.
- B. There is no continuous or at least periodically monitoring of air pressure differentials during production from the buffer room and ante room to the surrounding non-classified pharmacy area. Your pharmacist stated that he records a (b) (4) value from the magnehelic pressure gauges in the morning, which are located on the outside entrance into the ante room. These gauges are not viewable once inside the classified areas and no documentation could be provided showing that another employee is present during the formulation and filling of sterile drug products to monitor the magnehelic gauges.
- C. No calibration documentation could be provided for the (b) (4) magnehelic pressure gauges to monitor pressure differentials inside the classified areas mentioned above.

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SEE REVERSE OF THIS PAGE	Michael H. Tollon,	Investigator A	11/19/2014
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	ALTH AND HUMAN SERVICES
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200	10/27/2014 - 11/19/2014*
Maitland, FL 32751	FEI NUMBER
(407) 475-4700 Fax: (407) 475-4768	3011116100
Industry Information: www.fda.gov/oc/ind	ustry
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Andreas D. Dettlaff, Owner and CEO	
FIRM NAME	STREET ADDRESS
Absolute Pharmacy, LLC	16011 N Nebraska Ave suite 103
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lutz, FL 33549-6158	Outsourcing Facility
OBSERVATION 4	
Aseptic processing areas are deficient regarding the system	for monitoring environmental conditions.

Specifically,

- A. I could not verify that media used for collecting environmental samples is adequate to detect growth of violative organisms at low levels due to the following:
  - Your pharmacist has not included disinfectant neutralizers (e.g., (b) (4)
     when preparing in-house (b) (4) plates.
  - 2. Your pharmacist uses (b) (4) for growth promotion testing conducted for the media prepared in-house. No documentation could be provided showing this is an acceptable, consistent control.

# B. Personnel monitoring within all classified areas is not adequate based on the following:

- 1. Fingertip sampling uses the above mentioned inadequate media that is prepared in-house.
- 2. Your pharmacist's gowning materials have never been sampled after preparation of sterile drug products and his gowning technique has not been qualified.

C. Air and surface sampling within all classified areas is not adequate based on the following:

- 1. Sampling areas (air and surface) are not representative of the classified areas, since no scientific rationale could be provided for the current locations being sampled.
- 2. Viable particulate sampling was not conducted inside your Ante room, Gowning room, Buffer room, and laminar flow hood under dynamic conditions.
- 3. Viable surface sampling was not conducted inside your Ante room, Gowning room, Buffer room, and laminar flow hood during certification of these above classified areas.
- 4. Non-viable particulate sampling was not conducted under dynamic conditions.
- 5. Inadequately qualified in-house media (mentioned above) was used for sampling.

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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(407) 475-4700 Fax: (407) 475-4768	3011116100
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TO: Andreas D. Dettlaff, Owner and CEO	1
FIRM NAME	STREET ADDRESS
Absolute Pharmacy, LLC	16011 N Nebraska Ave
	suite 103
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lutz, FL 33549-6158	Outsourcing Facility
OBSERVATION 5	· · · · · · · · · · · · · · · · · · ·

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- B. No sporicidal agent is used to clean your classified areas, including the laminar flow hood where sterile drug products are prepared.

### **OBSERVATION 6**

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, gowning procedures are not being followed as well as gowning qualifications have not been conducted for your pharmacist that compounds sterile drugs in the Buffer room and under the laminar flow hood. For example, I observed inconsistent and inadequate gowning practices during this inspection as described below:

- A. There is no demarcation of the dirty and clean side of the Gowning room entering into the Buffer room. I observed that the pharmacist walked all over the Gowning room during his gowning.
- B. The pharmacist does not follow your SOP 9.100 "REQUIRED GARB FOR CLEAN ROOM FACILITY ACCESS", which states a sterile face mask should be worn. Your pharmacist stated he wears a face mask that is non-sterile while preparing sterile drug products. There is no evidence that your firm has purchased any sterile face masks to be used in the preparation of sterile drugs.
- C. I observed the pharmacist handling and placing his face mask and goggles on his face prior to washing his hands.

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SEE REVERSE OF THIS PAGE	1	Investigator N-A	11/19/2014
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	FO	NT OF HEALTH AND HUMAN SERVICES	
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TO: AI	of INDIVIDUAL TO WHOM REPORT ISSUED	nd CEO	
	e Pharmacy, LLC	stREET ADDRESS 16011 N Nebraska Ave suite 103	
	CODE, COUNTRY L 33549-6158	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
There are	<b>ATION 7</b> no written standards or specifications, m of processing to remove pyrogenic prope	nethods of testing, methods of cleaning, me rties.	thods of sterilization, and
Specific	ally,		
	The <b>(b) (4)</b> classware used in the filling of ste	has not been validated. This proces rile drug products.	s is used for all labora
	The (b) (4) inished product vials, rubber stop	have not been validated. This pers and caps used in the filling of s	
	Glass vials, caps, rubber stoppers, dentified in a way that would allo	and beakers sterilized and/or depyrow a trace back to the (b) (4)	ogenated in-house, are (b) (4)/ba
	ATION 8	n do not include appropriate laboratory det	muination of actinfactory.
		y and strength of each active ingredient pri	
Specific	ally,		
	Your firm has not validated sterilit formulations do not interfere with	ty and endotoxin testing to ensure su	bstances in your produ
-			iosumees in your prod
B. Y	or any of your liquid sterile drug	sting to determine the preservative (i products prior to distribution: vitam ride (MIC)+vitamin B12 and MIC+v	.e., <mark>(b) (4)</mark> ) co in B12,
B. M f N C. M	or any of your liquid sterile drug p Methionine/Inositol/Choline Chlor Your firm has never tested the pote products prior to distribution: Hun	sting to determine the preservative (ipproducts prior to distribution: vitam	.e., (b) (4) ) co in B12, vitamin B1+vitamin B terile (b) (4) drug otan II Acetate, and
B. M f N C. M	Action of your liquid sterile drug p Methionine/Inositol/Choline Chlor Your firm has never tested the pote products prior to distribution: Hun Sermorelin+Growth Hormone Rele Michael H. Tollon, I	sting to determine the preservative (i products prior to distribution: vitam ride (MIC)+vitamin B12 and MIC+v ency or reconstitution time of your s nan Chorionic Gonadotropin, Melan easing Peptide (GHRP)-2+GHRP-6	.e., (b) (4) ) co in B12, vitamin B1+vitamin B terile (b) (4) drug otan II Acetate, and

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(407) 475-4700 Fax: (407) 475-4768		3011116100
Industry Information: www.fda.gov/oc/ind	dustry	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
TO: Andreas D. Dettlaff, Owner and CEO		
FIRM NAME	STREET ADDRESS	
Absolute Pharmacy, LLC	16011 N Ne	ebraska Ave
	suite 103	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT	INSPECTED
Lutz, FL 33549-6158	Outsourcin	ng Facility

## **OBSERVATION 9**

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically for the compounding of sterile drugs at your firm, you could not provide documentation stating what steps were completed, when they were completed, and by whom.

### **OBSERVATION 10**

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, I could not verify hold times or the length of time it took to perform critical steps in the compounding of sterile drugs (e.g., Cyanocobalamin, Human Chorionic Gonadotropin, MIC+B12), such (b) (4) of the sterile drug products since batch production and control records were

incomplete.

### **OBSERVATION 11**

Each lot of a component, drug product containers, and closures liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

- A. Your firm has no qualified vendor program and no documentation could be provided showing you have qualified any of your bulk drug substance (e.g., (b) (4) .) or component suppliers.
- B. Your firm has not verified that any CoA test results are reliable for any incoming bulk drug substance used in the preparation of sterile drug products.

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555 Winderley Place, Suite 200       10/27/2014 - 11/19/2014*         Maitland, PL 32751       301116100         Industry Information: www.fda.gov/oc/industry       301116100         Note as D. Dettlaff, Owner and CEO       STRETACORES         Absolute Pharmacy, LLC       16011 N Nebraska Ave suite 103         Industry Information: www.fda.gov/oc/industry       STRETACORES         Absolute Pharmacy, LLC       16011 N Nebraska Ave suite 103         Intrace converse       Outsourcing Facility         Conversion       Outsourcing Facility         OBSERVATION 12       Outsourcing Facility's drug products do not include information required b section 503B(a)(10). Specifically,         1. Your firm's labels affixed to the drug products do not contain the date for which the avas compounded, as required by 503B(a)(10)(A)(iii)(V); and         2. The statement "Not for resale" is not present on certain drug product labels, as require by section 503B(a)(10)(A)(iii)(IX).         Examples include the following drug product labels: HCG Injection 5,000 USP Units/Vial; Cyanocobalamin USP 1,000mcg/mL; Sermorelin/GHRP-2/GHRP-6 10mg/3mg/3mg Vial; N +B12 25/50/50mg/mL + 20mcg/mL; and Melatonin II Acetate 10mg/Vial.         B. The containers from which the individual units of the drug are removed for dispensing or for administration do not adequately display the phone number to facilitate adverse event report (1-800-FDA-1088), nor does it display www.fda.gov/medwatch, as required by section 503B(a)(10)(B)(ii).         * DATES OF INSPECTION: <th></th> <th>F HEALTH AND HUM</th> <th></th>		F HEALTH AND HUM	
Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry Market Market Soft NSPECTION: 102: Andreas D. Dettlaff, Owner and CEO FREMARE Absolute Pharmacy, LLC Information: www.fda.gov/oc/industry Information: United Free Soft Soft Soft Soft Soft Soft Soft Soft	DISTRICT ADDRESS AND PHONE NUMBER	AND DRUG ADMINISTRAT	
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Industry Information: www.fda.gov/oc/industry         www.mid Grammon.rowHowReport Bodd         TO:       Andreas D. Dettlaff, Owner and CEO         RMMMME       Istner ADDRES         Absolute Pharmacy, LLC       Istner ADDRES         Corr, HAR. 2P CODE, COUNTRY       Induction and CEO         CORSERVATION 12       The labels of your outsourcing facility's drug products do not include information required b section 503B(a)(10). Specifically,         1.       Your firm's labels affixed to the drug products do not contain the date for which the owas compounded, as required by 503B(a)(10)(A)(iii)(V); and         2.       The statement "Not for resale" is not present on certain drug product labels, as require by section 503B(a)(10)(A)(iii)(IX).         Examples include the following drug product labels: HCG Injection 5,000 USP Units/Vial; Cyanocobalamin USP 1,000mcg/mL; Sermorelin/GHRP-2/GHRP-6 10mg/3mg/3mg Vial; N +B12 25/50/50mg/mL + 20mcg/mL; and Melatonin II Acetate 10mg/Vial.         B.       The containers from which the individual units of the drug are removed for dispensing or for administration do not adequately display the phone number to facilitate adverse event report (1-800-FDA-1088), nor does it display www.fda.gov/medwatch, as required by section 503B(a)(10)(B)(ii).         * DATES OF INSPECTION:         1027/2014(Mon), 10/28/2014(Twe), 10/29/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed), 10/30/2014(Thu),	Maitland, FL 32751		
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<ul> <li>Absolute Pharmacy, LLC</li> <li>Absolute Pharmacy, LLC</li> <li>IGOI1 N Nebraska Ave suite 103</li> <li>Investme.are concounter</li> <li>Intervestme.are concounter</li></ul>	NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	/industry	
Absolute Pharmacy, LLC       16011 N Nebraska Ave         Suite 103       NVEERABLISMENT INSPECTION:         CONVERTION 12       Outsourcing Facility         OBSERVATION 12       A. The labels of your outsourcing facility's drug products do not include information required b section 503B(a)(10). Specifically,         1. Your firm's labels affixed to the drug products do not contain the date for which the was compounded, as required by 503B(a)(10)(A)(iii)(V); and         2. The statement "Not for resale" is not present on certain drug product labels, as require by section 503B(a)(10)(A)(iii)(IX).         Examples include the following drug product labels: HCG Injection 5,000 USP Units/Vial; Cyanocobalamin USP 1,000mcg/mL; Sermorelin/GHRP-2/GHRP-6 10mg/3mg/3mg Vial; N +B12 25/50/50mg/mL + 20mcg/mL; and Melatonin II Acetate 10mg/Vial.         B. The containers from which the individual units of the drug are removed for dispensing or for administration do not adequately display the phone number to facilitate adverse event report (1-800-FDA-1088), nor does it display www.fda.gov/medwatch, as required by section 503B(a)(10)(B)(ii).         * DATES OF INSPECTION:         10/27/2014(Mon), 10/28/2014(Tue), 10/29/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed), 10/30/2014(			
Builte 103           CHY, BIAR, 2P CODE, COUNTRY           Lutz, FL 33549-6158           OBSERVATION 12           A. The labels of your outsourcing facility's drug products do not include information required b section 503B(a)(10). Specifically,           1. Your firm's labels affixed to the drug products do not contain the date for which the or was compounded, as required by 503B(a)(10)(A)(iii)(V); and           2. The statement "Not for resale" is not present on certain drug product labels, as require by section 503B(a)(10)(A)(iii)(IX).           Examples include the following drug product labels: HCG Injection 5,000 USP Units/Vial; Cyanocobalamin USP 1,000mcg/mL; Sermorelin/GHRP-2/GHRP-6 10mg/3mg/3mg Vial; N +B12 25/50/50mg/mL + 20mcg/mL; and Melatonin II Acetate 10mg/Vial.           B. The containers from which the individual units of the drug are removed for dispensing or for administration do not adequately display the phone number to facilitate adverse event report (1-800-FDA-1088), nor does it display <u>www.fda.gov/medwatch</u> , as required by section 503B(a)(10)(B)(ii).           * DATES OF INSPECTION: 10/27/2014(Mon), 10/28/2014(Tue), 10/29/2014(Wed), 10/30/2014(Thu), 11/03/2014(Mon), 11/04/2014(Tue), 11/12/2014(Wed),			Nehue also Arre
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SEE REVERSE OF THIS PAGE	Michael H. Tollon,	Investigator // //	*	11/19/2014
	EMPLOYEE(S) SIGNATURE	nA		DATE ISSUED