DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	5/31/2017-6/14/2017* FEI NUMBER 3008790859

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael A. Russin , CEO

FIRM NAME	STREET ADDRESS
Absolute Veterinary Compounding Pharmacy	2005 Fort Worth Hwy, #100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Weatherford, TX 76086-4779	Producer of Sterile and Non Sterile Drugs

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

a) Your firm has not conducted smoke studies under dynamic conditions of the ISO5 areas used to produce sterile injectable drug products to ensure that the movement of air during aseptic fill is adequate to prevent sterility risks.

b) Non sterile wipes are used to wipe down the surfaces of the ISO5 areas used in the production of your firm's injectable drug products. I observed your sterile technicians use non sterile wipes sprayed with commercially purchased (b) (4) to wipe the interior of the ISO5 area prior to aseptic fill, wipe the exterior of (b) (4) containing container/closures used to hold product, wipe down equipment used in aseptic process before placing in the ISO5 area and clean the ISO5 areas after aseptic fill.

c) Non sterile sporicidal disinfectants, (b) (4) and (b) (4) are used to disinfect the surfaces of the ISO5 areas used in the production of your firm's injectable drug products.

OBSERVATION 2

Drug product were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Patty P Kaewussdangkul, Investigator 6/14/2017 X Patty P Kaewussdangkul Patty P Kaewussdangkul Investigator Signed by: Patty P. Kaewussdangkul -S	6/14/2017

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Specifically,

Your firm sterilizes but does not depyrogenate glass vials or rubber stoppers used to hold sterile injectable drug products nor does your firm depyrogenate glassware used in the preparation of your sterile injectable drug products.

OBSERVATION 3

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

Specifically,

Your firm's sterile technician's garment consists of non-sterile booties, non-sterile hair net, non-sterile mask, sterile gowns and sterile gloves when entering the ISO7 cleanroom containing the ISO5 LAFH used to produce sterile injectable products. Your firm's current gowning practices leave the following areas exposed in the ISO7 cleanroom containing the ISO5 LAFH: forehead, eye area and neck.

I observed your sterile technician place (b) (6), (b) (7) (C) head containing a non-sterile hair net, non-sterile mask exposing (b) (6), (b) (7)(C) forehead, eye area and neck in the ISO5 LAFH while cleaning the ISO5 LAFH prior to the production of Iron Sucrose 20mg/m, Lot #053117.

OBSERVATION 4

Your firm's products are intended to prevent, mitigate or treat diseases in animals, they are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act. Furthermore, your products are not the subject of an approved new animal drug application, conditionally approved new animal drug application or index listing under sections 512, 571 and 572 of the FD&C Act. Therefore, the products are unsafe within the meaning of section 512(a) of the FD&C Act and adulterated under section 501(a)(5) of the FD&C Act such as but not limited to the following products:

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- Altrenogest 2.2mg/ml oral suspension
- Nitrofurazone 0.2% topical
- Diclofenac cream 1% (diclofenac sodium)

OBSERVATION 5

Your firm failed to conduct and document investigations of potency failures for the following compounded preparations that did not meet set potency specifications:

- Buserelin Acetate1mg/ml, Lot #LHRH052016 had potency results of 122.7%. (Specification (b) (4)%-(b) (4)%)
- Xylazine HCL 125mg/ml, Lot #XY102716 had potency results of 119.1. (Specification (b) (4)%-(b) (4)%)
- Folic Acid 50mg/ml, Lot #FA080916 had potency results of 88.8%. (Specification (b) (4)%-(b) (4)%)
- Omeprazole/Mistoprostol 228mg/0.14 mg/ml, Lot #OMMO101416 had potency results of 74.7%. (Specification (b) (4)%-(b) (4)%)
- Ketoprofen 100mg/ Glucosamine 100mg, Lot # KG101316. Glucosamine had potency results of 80.0% (Specification (b) (4)%-(b) (4)%)
- Testosterone Cypionate 200mg/ml/ Anastrozole 1mg/ml, Lot #TA083016. Anastrozole had potency results of 10.3%. (Specification (b) (4)%(b) (4)%)
- Triamcinolone 2mg Amikacin 50mg, Lot #TRIAMI071416. Amikacin had potency results of 72.6%. (Specification (b) (4)%-(b) (4)%)

In addition, Testosterone Cypionate 200mg/ml/ Anastrozole 1mg/ml was distributed to a customer.

***DATES OF INSPECTION**
5/31/2017(Wed),6/01/2017(Thu),6/02/2017(Fri),6/05/2017(Mon),6/06/2017(Tue),6/14/2017(Wed)

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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."