DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

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:

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your environmental monitoring (EM) of the ISO 5 Laminar Airflow Hood (LAFH) in Sterile Non-Hazardous Drug Suite and the ISO 5 Biological Safety Cabinet (BSC) in Sterile Hazardous Drug Suite is not performed on a frequent basis to demonstrate that the ISO 5 environment is adequate for the production of sterile drugs. EM was conducted on a (b) (4) basis including viable air sampling and surface sampling. For example, your firm performed EM in Sterile Hazardous Drug Suite on 6/21/2023 and 7/18/2023 and in Sterile Non-Hazardous Drug Suite on 6/14/2023 and 7/14/2023. Non-viable air monitoring is conducted (b) (4) during qualification of ISO classified areas. For example, the two most recent certifications of LAFH were issued on (b) (4) and (b) (4) ; however, no EM was conducted during manufacturing of each batch. During the period of 7/24/2023 to 8/23/2023, your firm received (b) (4) prescription orders for sterile compounded drug products. For example, your firm produced Atipamezole Hydrochloride @(b) (4) Mg/ML Injection, Lot# 04252023@(b) (4) on 4/25/2023 and Lot # 05252023(b) (4) on 5/25/2023. No EM was performed during aseptic compounding process for these batches.

B. Personnel monitoring does not follow your procedure. According to your SOP 3.03, Environmental Monitoring of the Cleanroom Facilities, Version Number 17.0, personal gloves shall be sampled at least (b) (4) , including when sterile compounding personnel complete, a (b) (4) sterile compounding medial fill, after garbing and prior to disinfecting gloves; however, your firm sampled personal gloves for microbiological testing only during media fill but not on a (b) (4) basis per your SOP requirement. For example, Technician (b) (6), (b) sampled gloves on 1/20/2023 and 7/5/2023 during media fill for sterile non-hazardous compounded drugs, but there was no (b) (4) sampling conducted in 2023. Also, personnel monitoring is not performed during the manufacturing of each batch.

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Taichun Qin	Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

C. On 8/23/2023, during the compounding of Acetyl-D-Glucosamine In Water for INJ, 200 MG/ML Injectable, Lot# 08232023@(b)(4) in the Sterile Non-Hazardous Drug Suite, it was observed sealed (b) (4) bags containing vials, stoppers or utensils placed in a movable cart in the ISO 7 buffer room were introduced into the ISO 5 LAFH one at a time by Technician (b)(6), (b), and then the outer layer of each bag was removed by Technician (b)(6), (b); however, surfaces of each outer layer bag were not sanitized with (b) (4) prior to be introduced into the ISO 5 LAFH by Technician (b)(6), (b).

D. During aseptic compounding of Acetyl-D-Glucosamine In Water for INJ, 200 MG/ML Injectable, Lot# 08232023@(b)(4) in the Sterile Non-Hazardous Drug Suite on 8/23/2023 and Histrelin (As Histrelin Acetate) @ 0.5 mg/ml Injection, Lot # 08252023@(b)(4) in the Sterile Hazardous Drug Suite on 8/25/2023, it was observed on both occasions Technicians forehead was not fully covered by a hairnet and hair on the back of the neck was exposed.

E. There is no air return vent in the Sterile Non-Hazardous Drug Suite. The return air blows out from the ISO 7 cleanroom directly to the unclassified non-sterile drug production area through an air filter taped on from the outside on all four sides of this cleanroom suite.

F. Your firm has not established and/or validated a hold time for supplies after depyrogenation. Your firm performed in-house depyrogenation of beakers and utensils used for producing sterile compounded animal drug products. For example, your firm used the depyrogenated glass beaker wrapped with (b) (4) to produce Detomidine HCL/Xylazine 2.5Mg/100Mg/ML Injectable, Lot# 05052023@(b)(4) on 5/5/2023;

Your firm stated that in general, a beaker after depyrogenation could be held for (b) (4); however this hold time has not been well established and validated. Also, your firm has established a (b) (4) hold time for vials placed in a pouch by operators used for producing sterile compounded drug products. For example, your firm produced Xylazine In Water For Injection@333 Mg/Ml Injectable, Lot# 04192023@(b)(4) on 4/19/2023 using a depryogenated (b) (4) dated 3/27/2023; however, you have not validated the (b) (4) hold time.

OBSERVATION 2
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	UQ	Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

Your firm has not performed sterility testing for any sterile compounded drug products to determine an extended beyond use date (BUD). For example, you firm has assigned an extended BUD for 180 days for Ammonium Sulfate 0.75% Injection, Adenosine Monophosphate 200 Mg/Ml Injection, L-Arginine HCL 200 Mg/Ml Injection and Xylazine (BASE) 333 Mg/Ml Injection based on potency testing; however, sterility testing was only conducted at release of a batch, but not during stability study, so there is no assurance sterility could be maintained throughout the shelf life of each product. An example of product label for Xylazine In Water For Injection@ 333 Mg/Ml Injectable, Lot# 04192023@[(b)(4)] (compounding date: 4/19/2023) associated with Rx [(b)(4), (b)(6), (b)(7)(C)] shows "Discard After 10/16/2023".

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

According to your SOP 9.010, The Quality Assurance Program, Version Number 12.0, potency test will be conducted for at least[(b)(4)]% of compounded formulations made (b) (4) for sterile drug products and at least [(b)(4)]% for non-sterile drug products; however, there is no assurance your finished drug products conform to product specifications from batch to batch without conducting appropriate testing. For example, your firm did not conduct potency testing for most batches of finished drug products prior to release, examples listed as follows:

Rx	Compounded Drug Name	Batch Number
(b) (6), (b) (7)(C)	Diclazuril/Levamisole In Oil @ 30MG/80MG/ML Suspension	#08072023@[(b)(4)]
	Doxycycline In Oil (FC) @ C 100MG/ML Suspension	#04182023@[(b)]
	Enrofloxacin > C 200MG/ML Paste	#05222023@[(b)(4)]
	Estradiol Cypionate In Sesame Oil @ C 2MG/ML Injectable	#C04112023@[(b)]
	Fluoxetine @ 200MG/Scoop Powder	#08032023@[(b)(4)]
	Gentamicin Sulfate/Ketoconazole/Dexamethasone Topical Ointment @ 0.3%/2%/0.1% Ointment	#07072023@[(b)(4)]

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	UCe	Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

(b) (4), (b) (6), (b) (7)(C) Histrelin (As histrelin Acetate) @ 0.5MG/ML Injectable #07112023@(b) (4)
Enrofloxacin 200 MG/ML Suspension 07272023@(b) (4) 07272023@(b) (4)

OBSERVATION 4
Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

During walk-through of the facility on 8/23/2023, contamination was observed in your sterile and non-sterile production areas for the following:

• Unknown yellow stains were observed on HEPA filters inside the ISO 5 LAFH used for producing sterile non-hazardous animal drug products in the Sterile Non-Hazardous Drug Suite.

• The frame of the HEPA filter inside the LAFH peeled off in the Sterile Non-Hazardous Drug Suite.

• Many white stains were observed on scales and walls of (b) (4) hoods (b) (4) used for producing sterile non-hazardous drug products.

• Unknown stains were observed on a scale inside the (b) (4) hood used for compounding of sterile hazardous drug products in the Sterile Hazardous Drug Suite.

• Unknown powders/residues were observed on a scale inside (b) (4) Hood (b) (4) used for producing non-sterile products while the hood was not in use on that day.

• Opened drink cans and drink cups with visible liquid and spoons were discarded in trash bins in the non-sterile production area.

• A filter used to filter supply air inside the wall of the ISO 7 Negative Pressure Clean Room next to the ISO 5 BSC looked dirty with apparently visible debris in Sterile Hazardous Drug Suite.

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 5

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

Your firm does not conduct microbiological testing of finished non-sterile drug products for both patient-specific prescriptions and office use. Your firm produces compounded non-sterile drug products for the following dosage forms:

Scoop powders
Oral liquids
Oral pastes
Topical creams
Topical ointments
Transdermal gels
Oral capsules
Otic preparations

For example, microbiological testing was not conducted for batches produced during the period of 5/23//2023 to 8/23/2023 prior to release for the following:

Rx	Drug Name	Lot#
(b) (6), (b) (7)(C)	Enrofloxacin 200mg/mL susp	07272023@(b)(4)
	Methimazole 5mg/0.1mL in Lipoderm Transdermal Gel	05302023@(b)(4)
	Enrofloxacin 150mg/mL in oil susp	07172023@(b)
	Praziquantel/Pyrantel/Fenbendazole 45.4mg/45.4mg/50mg/mL in oil susp	08152023@(b)(4)
	Acetazolamide 250mg/mL susp	06142023@(b)(
	Azithromycin 200mg/mL in oil susp	06092023@(b)(4)
	Enrofloxacin 200 mg/ml paste	06052023@(b)(

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick A. Wade, General Manager

FIRM NAME	STREET ADDRESS
Precision Equine, LLC	5301 Young St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bakersfield, CA 93311-8978	Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 6
Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

• Your firm does not perform identity testing for any bulk drug substances used for producing compounded animal drugs.

• Your firm purchased sterile water for injection (WFI) for compounding of sterile animal drug products; however, certificates of analysis are not validated to ensure conformity.

For example, sterile water for injection, USP, Lot # (b) (4) was used to compound Cimetidine in Water for Inj @150 Mg/Ml Injectable, Lot # 07052023@[(b)(4)] on 7/5/2023. Release of WFI is based on review of Certificate of Analysis without appropriate tests being conducted for validation.

OBSERVATION 7
Written records are not made of investigations into unexplained discrepancies.

Specifically,

Your firm did not conduct inspections of nonconformances for compounding of animal drug products, examples listed as follows:

• Many white stains were observed on surfaces of scales and walls of (b) (4) hoods (b) (4)) used for producing sterile non-hazardous drug products that could not be cleaned or removed. Your firm attributed the root cause to spill of a chemical - (b) (4) during production; however, there is no documented evidence showing your firm has conducted an investigation and risk analysis on its potential impact on product quality during compounding of sterile drug products.

• Unknown yellow stains were observed on HEPA filters inside the ISO 5 LAFH used for producing sterile non-

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE		Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	8/23/2023-8/25/2023; 8/28/2023-9/1/2023; 9/22/2023
	FEI NUMBER 3005698544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Patrick A. Wade, General Manager	
FIRM NAME Precision Equine, LLC	STREET ADDRESS 5301 Young St
CITY, STATE AND ZIP CODE Bakersfield, CA 93311-8978	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

hazardous animal drug products in the Sterile Non-Hazardous Drug Suite; however, there is no documented evidence showing your firm has investigated the root cause and its potential impact on product quality.

OBSERVATION 8
The quality control unit lacks the responsibility and authority to approve and reject all components.

Specifically,

Your firm used ungraded ingredients to produce non-sterile compounded drug products for animal use with examples listed for the following:

• Chromium Picolinate, Lot# (b) (4) used to produce Chromium Picolinate @10 MG/Scoop Powder, Lot# 190122/A on 6/6/2023

• (b) (4), Lot # (b) (4) used to produce Ponazuril In Oil > C 150Mg/Ml Suspension
These ingredients are ungraded according to the Certificate of Analysis and label from each supplier.

Amendment 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Taichun Qin	Taichun Qin, Investigator Sara H Gabel, Investigator **Julia N. Alvarez, Veterinary Medical Officer**	9/26/2023

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 judgement, 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."