DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US. Custom House 200 Chestnut St, Rm 900 Philadelphia, PA 19106 215-597-4390 Industry Information: www fda.gov/oc/industry	7/22/2019-8/09/2019* FEI NUMBER 3006708880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jaime Della Paula

FIRM NAME	STREET ADDRESS
Rapid Equine Solutions, LLC	31-A Mount Pleasant Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Aston, PA 19014	Producer of sterile and non-sterile drug products

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

OBSERVATION 1

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

Specifically, your firm did not perform testing to confirm the identify and strength of drug products. For example, the firm produced Toltrazuril Pyrimethamine Paste, Lot#20190509-11, BUD 11/05/2019 on 05/09/2019, of which (b) (4) of (b) (4) units were distributed. Following notice of an adverse reaction in 3 horses which were ultimately euthanized, FDA collected samples **on 06/05/2019** to conduct chemical analysis. The chemical analytical results are summarized in the tables below:

Amount toltrazuril detected:

Sub	Average (mg/mL)	Amount Declared	% Declared
Sub 15a	13.5mg/mL	416mg/mL	3%
Sub17a	11.2mg/mL	416mg/mL	3%

Amount pyrimethamine detected:

Sub	Average (mg/mL)	Amount Declared	% Declared
Sub15a	361mg/mL	17mg/mL	2122%
Sub17a	307mg/mL	17mg/mL	1808%

AMENDMENT 1

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OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds, insects and other vermin.

Specifically, during the walkthrough of your facility on 07/22/2019, approximately three insects where observed in the Laboratory Room which is adjacent to the ISO7 classified anteroom and non-sterile production anteroom. A roll of fly tape was also observed to be hanging from the ceiling near the sinks in the laboratory room. The following drug products were produced on that day: Folic Acid 10 mg/mL (b) (4) Lot#20190722-1, BUD: 01/18/2020, L-Carnitine 200 mg/mL (b) (4) Lot#20190722-4, BUD: 10/20/2019, Omeprazole 2g/15 mL Bismuth Salicylate 3 g/15 mL (b) (4) Paste, Lot#20190722-9, BUD:01/18/2020 and Dantrolene Suspension 100 mg/ml (b) (4) Lot#20190722-11, BUD: 08/21/2019

OBSERVATION 3

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

You have not established if the current cleaning method is capable of removing residuals of API, cleaning and sanitizing agents and objectionable organisms from multi-use equipment and utensils used to produce sterile products.

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OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

a) Aseptic manipulations occur in the (b) (4) hood, model (b) (4) serial (b) (4) that is not ISO5 classified. In addition, the blending of ingredients for Aspirin 40% (Sodium Salicylate 400mg/mL) Batch # 20190724-2 and Folic Acid 50mg/mL Batch # 20190724-3 was observed to occur on a stainless-steel table next to the (b) (4) hood away from the ISO7 HEPA filter. Non-sterile plastic wrap is reportedly used to cover containers of drug product after production processes have completed

b) The (b) (4) serial (b) (4) serial (b) (4) and the (b) (4) serial (b) (4) and (b) (4) model (b) (4) serial (b) (4) (used for sterilizing drug products and sterilizing and depyrogenating glass vials used to produce drug products are located in a room that lacks environmental controls to prevent contamination. Non-sterile foil wrap is reportedly used during (b) (4) processing and transfer between rooms to protect the components and drug products from contamination.

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OBSERVATION 5

Clothing of personnel engaged in the production of drug products is not appropriate for the duties they perform.

Specifically, non-sterile gowning articles are worn by the operators during the cleaning of surfaces and during the production of drug products in the sterile cleanroom. Gowning articles consist of a non-sterile half surgical mask (ear loop style), non-sterile face mask which covers the head and neck, a non-sterile non-shedding knee length frock that snaps closed in the front which is worn over scrubs which are worn off the street. On 07/24/2019, I observed the production of Aspirin 40% (Sodium Salicylate 400mg/mL) Batch # 20190724-2 and Folic Acid 50mg/mL Batch # 20190724-3.

OBSERVATION 6

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing, and holding.

Specifically, your firm uses the (b) (4) computer system to create and maintain production records. Batch templates are printed out and each page is individually placed into plastic zip closure bags for reference during sterile production procedures. Operators record information, processing notes and data (b) (4) (b) (4) test results) with a dry erase marker on the bag near the appropriate section, on the appropriate page of the batch record. At the end of drug production, the operator (b) (4) (b) (4) This could occur on the same day or the next day depending on when operations started. Additionally, there is no second person check of the weights of API and excipients measured before mixing procedures begin.

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OBSERVATION 7

There are no data to assure that procedures designed to prevent microbiological contamination of drug products purporting to be sterile perform as intended.

Specifically, the firm has not demonstrated that the terminal sterilization processes, including the (b) (4) process and the (b) (4) process for injectable drugs, produce drug products with an acceptable sterility assurance level. For example, the firm produced injectable drugs such as Aspiring 40% (Sodium Salicylate 400mg/mL) Batch # 20190724-2 and Folic Acid 50mg/mL Batch # 20190724-3, each of which were terminally sterilized by (b) (4) at (b) (4)

OBSERVATION 8

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

Specifically, review of the Certificate of Analysis for (b) (4) Cartridges lot# (b) (4) revealed that the firm is not conducting cartridge calibration per SOP P-604 Testing Via the (b) (4) System, v0 effective 2/25/2015, section 8.3.1.2. The following drug products Folic Acid 10 mg/mL (b) (4) Lot#20190722-1, BUD: 01/18/2020, L-Carnitine 200 mg/mL (b) (4) Lot#20190722-4, BUD: 10/20/2019, and Aspirin 40% (Sodium Salicylate 400mg/mL) Batch # 20190724-2 were released and dispensed to patients.

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