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

OBSERVATION 1
The ISO 5 classified area is located within a non-classified room (segregated production area).

Specifically, the ISO 5 classified (b)(4) located within a non-classified room which is not HEPA filter equipped. In addition, the ISO 5 classified (b)(4) is where sterile compounding operations are performed by personnel who move in and out of the unclassified room.

This is a Repeat Observation from previous inspection in 2016

OBSERVATION 2
Non-Pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, non-pharmaceutical grade components (b)(4) Corn Oil and (b)(4) Olive Oil were observed on the shelf with the firm's inventory barcode on the bottle. These components were used in the formulation of non-sterile veterinary drug products:

The following 1- prescription for veterinary drug was prepared using (b)(4) Corn Oil, Lot # (b)(4), Exp Date: 11/7/2019

Cyclosporine 2% Ophthalmic Solution in Corn Oil (VET) 2%, Log Lot#(b)(4), made date: 01/02/2018

The following 12- prescriptions for veterinary drugs was prepared using (b)(4) Olive Oil, Lot #: (b)(4), Exp Date: 02/02/2018

Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made
OBSERVATION 3

The use of sporicidal agents in the cleanroom and/or ISO 5 area is inadequate or infrequent.

a). The firm uses a re-sealable pouch of pre-wetted sterile wipes for cleaning of surfaces inside the ISO 5 classified which on 04/01/19, we observed that these pouches are used for more than one operation. There is no assurance that the sterile wipes remain sterile if the pouch is reused, and an expiration date after opening has not been established. A re-sealable pouch of pre-wetted wipes was observed in the ISO 5 classified on 04/01/19, but there was no production occurring at that time, and date of opening was not recorded on the pouch.

b). On 04/01/19, we observed brown spots forming on inside the ISO-5 classified used to hang
the IV bags. According to the pharmacist these brown spots are due to the cleaning (b)(4) corroding (b)(4) over time. This ISO 5 classified (b)(4) is used for aseptic filling of sterile drug products.

c). Adequate smoke studies under dynamic conditions have not been performed to demonstrate unidirectional airflow in the ISO 5 area. On 04/01/19, it was observed that the (b)(4) sterile wipes, and a (b)(4) were stored inside the ISO 5 classified (b)(4). According to the pharmacist these items are stored in the ISO 5 classified (b)(4) and not removed because they are needed for the (b)(4) to clean the classified (b)(4). The ISO 5 classified (b)(4) air pressure is turned off when not in use. The smoke study video and report provided, dated 12/13/18, do not contain these items within the (b)(4).