During an inspection of your firm (I) (we) observed:

**Observation 1**

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity. Specifically, finished product release testing does not include preservative content for injectable drug products. All drug products are sold as multi-dose units and include preservatives, such as (b)(4) and (b)(4).

**Observation 2**

Appropriate procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed. There is not adequate validation of the sterilization process. Specifically,

a) Pharmaceutical grade, (b)(4) are (b)(4) via a (b)(4) method which has not been validated. There are (b)(4) in use:

i. Per each (b)(4) Certificate of Quality, the (b)(4) Type (b)(4) have a (b)(4) specification of (b)(4) when using (b)(4). The (b)(4) being performed at Eagle uses (b)(4) as the (b)(4) and the (b)(4) specification from the manufacturer. There is no assurance the (b)(4) results are equivalent between the different
(b) (4) (i.e. (b) (4) ). Products which are (b) (4) using this (b) (4) include Brompheniramine Maleate, Cyanocobalamin, Ketorolac Tromethamine, Sodium Bicarbonate, and Vitachrom.

ii. Per each (b) (4) Certificate of Quality, the (b) (4) (b) (4) (b) (4) Type (b) (4) have a (b) (4) specification (b) (4) when using (b) (4) . The (b) (4) being performed at Eagle uses (b) (4) as the (b) (4) and the (b) (4) specification from the manufacturer. There is no assurance the (b) (4) results are equivalent between the different (b) (4) (i.e. (b) (4) (b) (4) Testosterone Cypionate is (b) (4) using this (b) (4)

b) Significant information is lacking in the records for the validated process used to sterilize injectable drug products. (b) (4) sterilization (b) (4) are available on the (b) (4) (b) (4) including (b) (4) at (b) (4) for (b) (4) and (b) (4) at (b) (4) for (b) (4) . The (b) (4) are not capable of printing or retrospectively showing the (b) (4) the batch records lack verification the correct (b) (4) were selected, and the (b) (4) used in each batch is designed to (b) (4) after (b) (4) at (b) (4) . Products which are sterilized using these (b) (4) include Betamethasone, Dexamethasone Acetate, Medroxyprogesterone Acetate, and Triamcinolone Acetonide.

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions. Specifically, there is no calibration of the (b) (4) gauges, thermometers, and (b) (4) used to monitor pressure differentials, temperature, and relative humidity for the ISO-classified areas used for sterile compounding.
OBSERVATION 4

Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions that would alter the safety, strength, quality, or purity of the drug product. Specifically, the analytical balance used for the weighing of drug components, an (b) (4) Model (b) (4), is not calibrated using a certified weight or routinely qualified for use. The (b) (4) weight used for (b) (4) internal calibration is lacking traceability and certification. The balance has not been qualified to verify its performance including precision/repeatability, off-center, and linearity testing.

*DATES OF INSPECTION:

05/01/2018 (Tue), 05/02/2018 (Wed), 05/04/2018 (Fri), 05/07/2018 (Mon), 05/08/2018 (Tue), 05/10/2018 (Thu), 05/11/2018 (Fri), 05/14/2018 (Mon), 05/18/2018 (Fri)