DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/01/2018-05/18/2018
	FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Zahir I. Hamid, General Manager/Pharmacist	
FIRM NAME Eagle Pharmacy Inc.	STREET ADDRESS 2200 Riverchase Center, Suite 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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:

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) (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) (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) (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) (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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Drug Investigator	5/18/2018

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(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.

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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)

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