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

1. The cycle parameters (b) (4) used for sterilization of product intended to be sterile are not adequately evaluated to ensure lethality to (b) (4) resistant microorganisms. Specifically, Your firm places a biological indicator in (b) (4) when sterilizing subcutaneous 12.5mg, 50mg, 92.5mg, 100mg Testosterone pellets and, 6mg, 25mg Estradiol pellets in the (b) (4) for (b) (4) at (b) (4) and (b) (4). The biological indicators are not processed or subjected to the same conditions as the pellets therefore there is no assurance that the (b) (4) cycle parameters utilized to sterilize the pellets are adequate. In addition, there is no documentation available that assesses the impact of sterilization on the compressed pellets (b) (4) lots of Testosterone pellets and (b) (4) lots of Estradiol pellets have been produced and distributed since May 2018.

2. Personnel were observed conducting aseptic manipulations in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product. Specifically, On 08/08/2018, during repackaging of one, 4ml vial of Avastin, Lot #32228610, injectable solution into (b) (4) syringes, containing 0.05ml/syringe of Avastin injectable solution, an operator was observed to place his hand(s) directly above the un-capped, open vial of 4ml Avastin single dose injectable solution, blocking unidirectional air flow while in the Class 100 (b) (4) Laminar Air Flow Workstation #1.

3. Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically, Your firm uses (b) (4) as a component in the production of Benazepril 2.5mg/ml suspension, Methimazole 10mg/ml suspension, Enalapril 5mg/ml suspension, Amlodipine 1.25mg/ml suspension, and Furosemide 10mg/ml suspension.