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

OBSERVATION 1
The (b)(4) is not always conducted for each lot of sterile drug products. Sterile drug products are produced by the firm from non-sterile API via (b)(4) under aseptic processing. There is no sterilization of finished drug products. The firm does not always conduct (b)(4) used to produce sterile drug products.

For example, Testosterone Cypionate 200mg/mL, Lot# 06/16/2016:08/16 was produced via (b)(4) and aseptic processing. There was no evidence that testing was conducted to (b)(4) During the inspection, the firm discontinued the production of sterile drug products indefinitely.

OBSERVATION 2
The firm has not demonstrated that the aseptic filling and closing operations are adequate to produce sterile drug products. Specifically, there have been no media fill process simulations performed in the firm's cleanroom and ISO Class 5 Hood. During the inspection, the firm discontinued the production of sterile drug product indefinitely.

OBSERVATION 3
Room air pressure differentials are not monitored during each production of aseptically processed sterile drug products. The firm's cleanroom suite and ISO Class 5 Hoods used to produce sterile drug products lack gauges or other devices to measure and/or monitor the air pressure differentials. Air pressure differentials are only measured and recorded (b)(4) During the inspection, the firm discontinued the production of sterile drug products indefinitely.