DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 1**

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, validation/verification of the cleaning methods for tools and equipment used in the manufacture of pellet drug products has not been proven. Data examined for the cleaning from testosterone/cholesterol pellets and from progesterone pellets have inappropriate acceptance criteria.

**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

A.) An employee in the blending/granulation room (ISO 8) of cleanroom was observed on 09/09/2019 with a beard cover that did not completely cover the beard.

B.) On the same day, an umbrella was observed inverted on a plastic tray. Both the umbrella and tray were located in an unclassified area reserved for temporary storage of quarantine non-ingredient materials such as caps and vials.

**DATES OF INSPECTION**

9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu), 9/13/2019(Fri), 9/19/2019(Thu), 9/20/2019(Fri)

**AMENDMENT 1**

SEE REVERSE OF THIS PAGE

Alan P Kurtzberg, Investigator

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9/20/2019