DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically, your firm produces highly potent drugs that includes, but not limited to Progesterone, Testosterone, Estradiol, Estriol, or a combination of these drug products using powder Active Pharmaceutical Ingredients (APIs) and other excipients. Utensils such as capsule-filling metal and plastic plates used in the compounding operations of these highly potent drugs are not dedicated and are not adequately cleaned with appropriate cleaning agents prior to use on non-potent drug substances. Further,

a) Your firm currently utilizes household dish liquid detergent and potable water for cleaning of utensils used in the processing of highly potent drug substances, including capsule-filling and related utensils.

b) No cleaning procedure has been established to demonstrate how cleaning of shared utensils used in the processing of drug substances should be performed to prevent cross-contamination.
OBSERVATION 2
Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically, you failed to provide maintenance and qualification records for the powder-hoods that your firm uses to process drug products to ensure that they adequately operate as intended. Further, the powder-hoods are equipped with non-pharmaceutical grade filters which you failed to prevent from potentially cross-contaminating other drug products. Moreover, the powder hoods are used to capsule fill or process both highly potent (Progesterone, Testosterone, Estradiol, etc.) and non-potent (Budesonide, Lidocaine, Benzocaine, etc.) drug products and these are not adequately designed to be cleaned in between capsule-filling operations of highly potent and non-potent drug substances.

OBSERVATION 3
Specific identification tests are not conducted on components that have been accepted based on the supplier’s report of analysis.

Specifically, some of the oral and topical drug products compounded by your firm for human and veterinary use are made using water. Your firm has no documentation of any testing performed (analytical or microbiological) to show that the water at least/meets the specification for purified water. An example of a drug reconstituted with water and dispensed by your firm for human consumption includes:
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Renee T. McCarthy, PharmD , Owner

FIRM NAME
Cape Drugs

STREET ADDRESS
1384 Cape St Claire Rd

CITY, STATE, ZIP CODE, COUNTRY
Annapolis, MD 21409-5325

TYPE ESTABLISHMENT INSPECTED
Producer of Non-Sterile Drug Products

a) Vancomycin 125mg/5mL (b) (4) Oral Solution, Lot# 123365, produced on 11/02/17

b) Vancomycin 250mg/5mL (b) (4) Oral Solution, Lot# 125714, produced on 12/15/17

*DATES OF INSPECTION
1/02/2018(Tue), 1/03/2018(Wed), 1/05/2018(Fri), 1/09/2018(Tue), 1/10/2018(Wed), 1/22/2018(Mon)

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Zakaria I Ganiyu, Investigator

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