DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	1/2/2018-1/22/2018* FEI NUMBER 3004562873

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

FIRM NAME	STREET ADDRESS
Cape Drugs	1384 Cape St Claire Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annapolis, MD 21409-5325	Producer of Non-Sterile Drug Products

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 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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Zakaria I Ganiyu, Investigator	X Zakaria I Ganiyu Investigator Signed By: Zakaria I. Ganiyu -S Date Signed: 01-22-2018 10:54:01	1/22/2018

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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 (b) (4) 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 (b) (4) 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 (b) (4) 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 (b) (4) water. Your firm has no documentation of any testing performed (analytical or microbiological) to show that the water at least/at minimum meets the specification for purified water. An example of a drug reconstituted with (b) (4) water and dispensed by your firm for human consumption includes:

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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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