DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	1/5/2016-1/13/2016*
	FEI NUMBER 3011755158

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Marvin O. McCord , Owner	
FIRM NAME Carlton's Dunwoody Pharmacy Corp	STREET ADDRESS 5484 Chamblee Dunwoody Rd
CITY, STATE, ZIP CODE, COUNTRY Dunwoody, GA 30338-4133	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drugs

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 WE OBSERVED:

OBSERVATION 1

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no stability data to support the expiration or beyond use dates assigned to several of your non-sterile drug products. In addition, the below products were assigned expiration dates that surpassed that of the Active Pharmaceutical Ingredients (APIs).

a) Biest(80/20)/Progesterone/Testosterone 2.5 MG/100MG/5MG Capsule, Lot #12162015@1, Expiration Date: 12/15/16 was produced with the below APIs.

1. Estradiol (b) (4) (b) (4)
2. Testosterone (b) (4) Expiration Date: (b) (4)

b) Triest(80/10/10)/Progesterone 1.35MG/110MG Capsule, Lot #12292015@2, Beyond use Date: 12/23/2016 was produced with the below APIs:

1. Estrone (b) (4) (b) (4) , Expiration Date: (b) (4)
2. Estradiol (b) (4) Lot #(b) (4) Expiration Date: (b) (4)

c) Budesonide, 1MG Capsule, Lot #09142015@1, Expiration Date: 9/13/2016 was produced with the below API.

1. Budesonide (b) (4) Lot #(b) (4) Expiration Date: (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamara J Henderson, Investigator Rachael L Cook, Investigator	1/13/2016 X Tamara J Henderson Tamara J Henderson Investigator Signed by: Tamara Henderson -S	DATE ISSUED 1/13/2016

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OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm has not conducted finished product testing on any of the non-sterile drug products you have produced to ensure the products have the strength and quality they purport.

OBSERVATION 3

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity , strength , quality and purity of drug products.

Specifically, your quality control unit has not established any written procedures relevant to the production of your non-sterile drug products. There are no procedures for testing, complaint handling, recalls, cleaning, and maintenance of your facility and equipment.

OBSERVATION 4

The calibration of instruments is not done at suitable intervals in accordance with an established written program and with provisions for remedial action in the event accuracy and/or precision limits are not met .

Specifically, your firm has failed to calibrate your (b) (4) calibration weight and the (b) (4) (b) (4) balances used to weigh active pharmaceutical ingredients and components for your drug products. Additionally, there are no written procedures describing the requirements for the calibration of the balances and calibration weight.

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OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch .

Specifically, the "Compounding Log Sheet" used for (b) (4) Lot #(b) (4) Topical Anesthetic Lot #090315, and Hydroquinone4%/Tretinoin0.05% Cream Lot #06202015A do not include documentation that each step in the drug production procedure is accomplished as evidenced by the lack of a review and approval by the quality control unit.

*DATES OF INSPECTION

1/05/2016(Tue),1/06/2016(Wed),1/07/2016(Thu),1/11/2016(Mon),1/13/2016(Wed)
1/13/2016

X Rachael L Cook
Rachael L Cook
Investigator
Signed by: Rachael L. Cook -S

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	Tamara J Henderson, Investigator Rachael L Cook, Investigator 1/13/2016 X Tamara J Henderson Tamara J Henderson Investigator Signed by: Tamara Henderson -S	1/13/2016