

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	DATE(S) OF INSPECTION 4/8/2019-4/12/2019*
	FEI NUMBER 3011755158

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Leslie D. Juhn, Pharmacy Manager

FIRM NAME Concord, Inc. dba Carlton's Dunwoody Pharmacy	STREET ADDRESS 5484 Chamblee Dunwoody Rd, Suite B-19
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CITY, STATE, ZIP CODE, COUNTRY Dunwoody, GA 30338-4133	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products
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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

You produced highly potent drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, your cleaning procedure is inadequate in that it does not include a cleaning agent to deactivate the hormonal drug products produced at your facility.

***DATES OF INSPECTION**

4/08/2019(Mon), 4/09/2019(Tue), 4/12/2019(Fri)

X Tamara J Henderson
Investigator
Signed By: Tamara Henderson -S
Date Signed: 04-12-2019 13:56:22

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamara J Henderson, Investigator Veronica Fuentes, Investigator	Veronica Fuentes Investigator Signed By: Veronica Fuentes -S Date Signed: 04-12-2019 13:55:48 X	DATE ISSUED 4/12/2019