

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	<small>DATE(S) OF INSPECTION</small> 4/8/2019-4/12/2019*			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Leslie D. Juhn, Pharmacy Manager				
<small>FIRM NAME</small> Concord, Inc. dba Carlton's Dunwoody Pharmacy	<small>STREET ADDRESS</small> 5484 Chamblee Dunwoody Rd, Suite B-19			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Dunwoody, GA 30338-4133	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Non-Sterile Drug Products			
<p>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.</p>				
<p>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.</p> <p>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.</p>				
<p>*DATES OF INSPECTION 4/08/2019(Mon), 4/09/2019(Tue), 4/12/2019(Fri)</p>				
<table style="width: 100%; border: none;"> <tr> <td style="border: none; width: 150px;"> X <small>Tamara J Henderson Investigator Signed By: Tamara Henderson -S Date Signed: 04-12-2019 13:56:22</small> </td> <td style="border: none; width: 600px;"></td> </tr> </table>			X <small>Tamara J Henderson Investigator Signed By: Tamara Henderson -S Date Signed: 04-12-2019 13:56:22</small>	
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<p>SEE REVERSE OF THIS PAGE</p>	<small>EMPLOYEE(S) SIGNATURE</small> Tamara J Henderson, Investigator Veronica Fuentes, Investigator	<small>DATE ISSUED</small> 4/12/2019		
<table style="width: 100%; border: none;"> <tr> <td style="border: none; width: 150px;"> X <small>Veronica Fuentes Investigator Signed By: Veronica Fuentes -S Date Signed: 04-12-2019 13:55:48</small> </td> <td style="border: none; width: 600px;"></td> </tr> </table>			X <small>Veronica Fuentes Investigator Signed By: Veronica Fuentes -S Date Signed: 04-12-2019 13:55:48</small>	
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