



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	<small>DATE(S) OF INSPECTION</small> 11/26/2018-11/29/2018  <small>FEI NUMBER</small> 3014539091	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> April N Stringer, Compounding RPH		
<small>FIRM NAME</small> Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc.	<small>STREET ADDRESS</small> 240 S. 13th Ave	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Laurel, MS 39440-4226	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Non-Sterile Drugs	
<p>A. Triple H cream lot AJCECABI@6 that contains testosterone</p> <p>B. Progesterone capsules 100 mg lot BBCHCABI@1</p> <p>C. Progesterone capsules 150 mg lot BCBBCABH@8</p>		
<p><b>OBSERVATION 3</b></p> <p>Personnel did not change gloves frequently enough to prevent contamination.</p> <p>Specifically, during the drug preparation of progesterone capsules 100 mg lot BBCHCABI@1 gloves that had visible progesterone powder were used to move and use the "compounding room" stools and computer equipment to include the mouse and keyboard.</p>		
<p><b>OBSERVATION 4</b></p> <p>Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.</p> <p>Specifically, during the drug preparation of progesterone capsules 100 mg lot BBCHCABI@1 utensils and the (b) (4) count capsule machine that had visible progesterone powder were placed onto two of the "compounding room" stools after use. The "compounding room" did not have an identifiable location to place used equipment to prevent cross-contamination prior to cleaning.</p>		
<p><b>OBSERVATION 5</b></p> <p>Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.</p>		
<p><b>SEE REVERSE OF THIS PAGE</b></p>	<small>EMPLOYEE(S) SIGNATURE</small> Joanne E King, Investigator  <div style="text-align: right; font-size: small;">                         Joanne E King                          Investigator                          Signed By 1300174867                          Date Signed 11-29-2018 14 25 43                          X _____                     </div>	<small>DATE ISSUED</small> 11/29/2018

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<p>Specifically, five capsules of the progesterone 150 mg sustained release (SR) caps lot BCBBCABH@8 were tested for potency. On 1/25/2018, the results were reported as 88% which is below the (b) (4)% specification for this formulation. There is no documentation to support how this information was evaluated and you continued to distribute the capsules until 3/28/2018 which is after these test results were reported. In addition you do not preform a confirmation of weight test on a representative percentage of capsules that you prepare to determine that the fill weight for each capsule is the same.</p>		
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