

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 11/26/2018-11/29/2018
	FEI NUMBER 3014539091

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
April N Stringer, Compounding RPH

FIRM NAME Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc.	STREET ADDRESS 240 S. 13th Ave
--	-----------------------------------

CITY, STATE, ZIP CODE, COUNTRY Laurel, MS 39440-4226	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 I OBSERVED:  
OBSERVATION 1**

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

Specifically, your operations include the preparation of non-sterile drug products that contain the anti-neoplastic agent fluorouracil such as fluorouracil/aloec 5%/0.1% lot BBBFCABI@2 using reusable equipment that is cleaned using municipal water, (b) (4) soap and rack or dishwasher heated drying. Working surfaces and utensils are wiped down using (b) (4). You do not have documentation do show that these methods are effective in removing and neutralizing fluorouracil residues.

**OBSERVATION 2**

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, work surfaces and reusable equipment such as spatulas, (b) (4) mortar pestle) and standard mixing containers are used to prepare non-sterile oral and topical drug products that contain hormones. This is reusable equipment that is cleaned using municipal water, (b) (4) soap and air or dishwasher drying. This equipment and working surfaces in the (b) (4) hood are wiped down using (b) (4). You do not have documentation do show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations are as follows:

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Joanne E King, Investigator	Joanne E King Investigator Signed By 1300174967 Date Signed 11-29-2018 14 25 43 X _____	DATE ISSUED 11/29/2018

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 11/26/2018-11/29/2018
	FEI NUMBER 3014539091

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
April N Stringer, Compounding RPH

FIRM NAME Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc.	STREET ADDRESS 240 S. 13th Ave
--	-----------------------------------

CITY, STATE, ZIP CODE, COUNTRY Laurel, MS 39440-4226	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs
---	---

- A. Triple H cream lot AJCECABI@6 that contains testosterone
- B. Progesterone capsules 100 mg lot BBCHCABI@1
- C. Progesterone capsules 150 mg lot BCBBCABH@8

**OBSERVATION 3**

Personnel did not change gloves frequently enough to prevent contamination.

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.

**OBSERVATION 4**

Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

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.

**OBSERVATION 5**

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.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Joanne E King, Investigator	Joanne E King Investigator Signed By 1300174867 Date Signed 11-29-2018 14 25 43 X _____	DATE ISSUED 11/29/2018

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 11/26/2018-11/29/2018
	FEI NUMBER 3014539091

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
April N Stringer, Compounding RPH

FIRM NAME Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc.	STREET ADDRESS 240 S. 13th Ave
--	-----------------------------------

CITY, STATE, ZIP CODE, COUNTRY Laurel, MS 39440-4226	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs
---	---

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 perform 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.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Joanne E King, Investigator	Joanne E King Investigator Signed By 1300174867 Date Signed 11-29-2018 14 25 43 X _____	DATE ISSUED 11/29/2018