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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| Dallas District Office<br>4040 N Central Expressway, Suite 300<br>Dallas, TX 75204<br>(214) 253-5200<br>Industry Information: www.fda.gov/oc/industry | 4/27/2015 - 5/11/2015 |
| | FEI NUMBER<br>3011286375 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Larketta J. Scarbrough-Swofford, Co-owner and Pharmacist

| FIRM NAME | STREET ADDRESS |
|---|---|
| Abrams Royal Pharmacy II, LLC | 4909 West Park Blvd., Ste. 177 |
| CITY, STATE AND ZIP CODE<br>Plano, TX 75093 | TYPE OF ESTABLISHMENT INSPECTED<br>Producer of Drug Products |

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) (WE) OBSERVED:

OBSERVATION 1
Your firm has not established appropriate testing and release procedures and controls to ensure finished drug products conform to satisfactory identity and strength prior to release.

Specifically,

1. Your firm does not conduct potency testing for any of the drug products produced by your firm. Listed are examples of drug products your firm produced and distributed within (b) (4) without potency testing:

a. Testosterone-Q Pump 75mg/mL Cream, Lot 04242015@35, Distributed 4/24/2015
b. Estradiol-U Pump 15mg/mL Cream, Lot 04232015@5, Distributed 4/23/2015
c. Piroxicam 3mg Capsule, Lot 04172015@34, Distributed 4/17/2015
d. Cortisol-MC 10mg Capsule, Lot 04012015@45, Distributed 4/10/2015
e. Liothyronine (T3)-MC 375mcg Capsule, Lot 04062015@48, Distributed 4/6/2015

2. Your firm does not conduct testing to assure product uniformity and homogeneity.

OBSERVATION 2
Your firm has not established procedures and controls to ensure finished drug product's Beyond Use Dates (BUD) are appropriate.

Specifically, your firm does not have a written stability testing program to determine BUDs placed on all your drug products. For example,

1. Your firm does not have documentation to justify the following BUDs placed on the drug products (b) (4) produced by your firm. They include, but are not limited to:

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | Lisa Jennings | Lisa Jennings, Investigator<br>Jason R. Caballero, Investigator | 5/11/2015 |

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a. Cortisol-MC 5mg Capsule, Lot 04102015@6, BUD 180 Days
b. Cortisol-MC 10mg Capsule, Lot 04012015@45, BUD 180 Days
c. Cortisol-MC 15mg Capsule, Lot 12222014@24, BUD 180 Days
d. Cortisol-MC 20mg Capsule, Lot 03242015@48, BUD 180 Days
e. Cortisol-MC 25mg Capsule, Lot 04132015@13, BUD 180 Days
f. Liothyronine (T3)-MC 150mcg Capsule, Lot 03232015@29, BUD 166 Days
g. Thyroid-P (4 Grain) 240mg Capsule, Lot 04222015@21, BUD 166 Days
h. Testosterone-Q Pump 30mL 20mg/mL Cream, Lot 03192015@16, BUD 180 Days
i. Progesterone RDT 50mg Tablet, Lot 02042015@12, BUD 180 Days

OBSERVATION 3

Your firm has not established procedures to ensure appropriate clothing is worn by your personnel engaged in producing finished drug products.

Specifically, on 4/27/2015, your firm's technician did not wear the required apparel while producing Test/Prog-Q 200/25 mg/mL P, Lot 04242015@31, Beyond Use Date 9/23/2015, in the Lab. He did not wear a beard cover. In addition, he did not wear his face mask correctly. The mask rested under his nose instead of over it. According to SOP 9.130, "Required Garb for Non-Sterile Compounding Area", Date Effective 09-27-12, Version 1.0, Section 9.1 and 9.1.2, "Prior to non-sterile compounding activities, all personnel must: Don a clean hair net, beard cover (if necessary) and face mask".

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | Lisa Jennings | Lisa Jennings, Investigator<br>Jason R. Caballero, Investigator | 5/11/2015 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."