DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Baltimore District Office 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Industry Information: www.fda.gov/oc/industry	12/07/2017-12/12/2017
	FEI NUMBER 3004514280

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Simeon J. Georgiou, Owner/Pharmacist

FIRM NAME	STREET ADDRESS
Professional Arts Pharmacy	2015 Lord Baltimore Dr.
CITY, STATE AND ZIP CODE Baltimore, MD 21244	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile 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 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. Specifically, your firm's acceptable range for potency is (b) (4) However, drug products that were sub-potent or super-potent were prepared and dispensed. For example:

1. Rx (b) (6) , Progesterone 100mg suppositories, dated 03/30/2017 was sub-potent. This drug product is for human use. Testing performed on 04/18/2017 resulted in 76.4% potency. The product was re-tested on 05/02/2017 and with a potency result of 84.6%. An additional re-test on 06/12/2017 resulted in 79.9% potency.

2. Rx (b) (6) , Budesonide 1mg capsules, dated 03/15/2017 was sub-potent. This drug product is for veterinary use. Testing performed on 03/27/2017 resulted in a potency of 84.2%.

3. Rx (b) (6) , Fluoxetine 30mg capsules, dated 08/31/2017 was super-potent. This drug product is for veterinary use. Testing performed on 09/16/2017 resulted in a potency of 113%.

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SEE REVERSE OF THIS PAGE		Djamila Harouaka, Investigator Sena G. Z. Dissmeyer, Investigator	12/12/2017

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OBSERVATION 2

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

On 12/12/2017, a pharmacy technician produced cortisone 5mg capsules pursuant to Rx (b) (6) . After production of this prescription, the technician cleaned the work surface and apparatus with (b) (4) . I (SD) observed the bottom of the technician's lab coat sleeve come into contact with white powder that was on the work surface. After cleaning, the technician proceeded to produce theophylline 130mg capsules pursuant to Rx (b) (6) , while wearing the same lab coat.

Your firm produces capsules containing:

(1) hormones such as progesterone, estradiol, thyroid hormones (T3 and T4) and testosterone
(2) steroids such as cortisone and prednisolone
(3) hazardous drugs such as chlorambucil, azathioprine, cyclophosphamide, and hydroxyurea

The apparatus used to prepare capsules for hazardous drugs and highly potent drugs is non-dedicated. The apparatus is cleaned with soap and water following the preparation of hazardous drugs or capsules with colors. The apparatus is routinely cleaned with (b) (4) and periodically cleaned with dish soap and water.

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OBSERVATION 3

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically,

(A) Simple syrup lot (b) (4), prepared on 11/20/2017, was made using (b) (4) . Amlodipine Besylate liquid stock lot (b) (4), prepared on 12/05/2017, was made using simple syrup lot (b) (4).

(B) (b) (4) solution lot (b) (4), prepared on 10/10/2017, was made using simple syrup. The lot number of the simple syrup used was not recorded. Lot (b) (4) of (b) (4) , incorrectly recorded as (b) (4), was used to make Gabapentin lot (b) (4) on 12/05/2017. Gabapentin liquid stock lot (b) (4) was used to make Gabapentin 100mg/ml suspension #30 pursuant to Rx (b) (6) on 12/11/2017.

(C) Master Suspension lot (b) (4), prepared on 11/16/2017, was made using (b) (4) water. Master Suspension lot (b) (4) was used to make Tylosin Tartarate stock solution lot (b) (4) on 11/24/2017. This stock solution was used to prepare Tylosin 100mg/ml solution #100 pursuant to Rx (b) (6) on 12/04/2017.

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