DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Ste 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	07/30/2018, 07/31/2018, 08/01/2018, 08/02/2018, and 08/07/2018
	FEI NUMBER 3005946041

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jeffrey S. Langer, Owner/Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
The Pet Apothecary LLC	407 West Silver Spring Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Milwaukee, WI 53217	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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

Beta-lactam drugs are produced in non-designated areas sharing the same work surfaces and equipment that are also used to produce non-beta-lactam drugs, of which are not cleaned/sanitized with bleach and isopropyl alcohol (70%) to provide adequate inactivation of the drug. For example, the following prescriptions for beta-lactam drugs were produced on work surfaces and equipment that were cleaned/sanitized with (b) (4)) and later used to produce non-beta-lactam drugs, which may be at risk of cross-contamination:

-Rx (b) (6) Amoxicillin capsules 150mg on 4/25/2018
-Rx (b) (6) Cyclophosphamide capsules 13mg on 7/19/2018
-Rx (b) (6) Cyclosporine liquid suspension 50mg/mL on 7/13/2018

Additionally, there are no controls or procedures in place for production of beta-lactam drugs to be contained within a separate air handling unit. The use of (b) (4) HEPA-filtered containment hoods for production of beta-lactam drugs is optional, as reported by the pharmacist-in-charge.

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	Michael Y. Philopoulos	Michael Y. Philopoulos, Investigator	08/07/2018

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OBSERVATION 2

Cleaning methods are not established in a written procedure nor are appropriate cleaning agents specified.

Specifically,

a.) Drug product production equipment such as capsule filling trays and spatulas/mortars/pestles/spinners are not rinsed with purified water and/or sanitized with appropriate sanitizing agents after cleaning with hot water and dish soap.

b.) There are no defined/labeled areas for storage of "clean" and "unclean" drug production equipment/utensils and cloth cleaning towels. These items were observed on counter tops in the cleaning area by the 2-compartment sink without identification of "clean" or "unclean" status or any other unique identifier.

c.) There are no cleaning procedures defining what cleaning/sanitizing agents are acceptable and when/how to use them. For example, (b) (4) is used to clean/sanitize benchtops and analytical balances after use for each drug product produced (witnessed after production of budesonide capsules 1mg: Rx (b) (6) and metronidazole capsules 62.5mg: Rx (b) (6)); however, (b) (4) may also be used to clean/sanitize benchtops as well, as reported by the pharmacist-in-charge. Additionally, there are no specified cleaning/sanitizing agents (bleach and IPA 70%) or instructions for cleaning work surfaces and equipment after production of beta-lactam containing drug products.

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OBSERVATION 3

Analytical balances, used for weighing drug materials/components, are not uniquely identified nor appropriately calibrated on a periodic basis, nor periodically weight checked with an appropriate certified weight set. Examples include, but not limited to:

- (b) (4) (Model (b) (4)
- (b) (4) (Model (b) (4))
- (b) (4) ((b) (4))
- (b) (4) (S/N (b) (4))

No calibration or maintenance records for the aforementioned analytical balances, used for drug product production, were provided. During production of a prescription fill for budesonide capsules 1mg on 7/27/2018 (Rx (b) (6) it was observed that a non-calibrated analytical balance was used.

OBSERVATION 4

Prescription production records are deficient in that they do not include the following:
-name of manufacturers, lot numbers, and expiry dates of all materials/components used.
-identification of any automated, mechanical, or electronic equipment that is used during drug processing; e.g. analytical balances.
-proof or second-check verification of weights/volumes recorded for each component used.

For example, the prescription production records for a prescription fill of a tramadol suspension 20mg/mL (Rx (b) (6) on 7/09/2018 lack these aforementioned items.

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OBSERVATION 5

Your pharmacy does not have an established training program for technicians nor do you maintain any training record documentation for on-the-job training that was provided to them. Dosage forms prepared by technicians range from aqueous solutions, oils/suspensions, capsules, chew treats, eye drops, to transdermals.

OBSERVATION 6

Appropriate protective apparel is not always worn by technicians to protect drug products from contamination during production. Specifically, several technicians were observed producing drug formulations without hair nets and/or designated gowning/apparel during the inspection. For example, during production of metronidazole capsules 62.5mg (Rx (b) (6) on 7/31/2018 a technician with long hair was observed without a hairnet.

OBSERVATION 7

Your pharmacy does not have established written procedures for handling and maintaining records for quality-related events, such as for complaints, ADE/MedWatch reporting, recalls, deviations, and investigations. For example, no records for a complaint investigation involving a prescription refill of phenobarbital capsules 6mg on 10/19/2017 (Rx (b) (6) for super potency were provided.

OBSERVATION 8

Your pharmacy does not have established written procedures or adequate controls in place for receipt and storage of materials/components used to produce drug products.

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Specifically,

a.) Materials/components used to produce drugs are not all classified and/or identified upon receipt as either being non-hazardous, hazardous/highly potent, containing beta-lactams, or controlled substances.

b.) Storage of hazardous/highly potent materials, controlled substances, and beta-lactam containing materials are not always segregated or accounted for appropriately.

c.) Inventory records for materials/components used to produce drugs are not maintained for those currently on-hand.

d.) Pertinent information on incoming materials/components used to produce drugs, such as the name of manufacturers and whether they are an approved supplier, lot numbers, and if an accompanying CoA for bulk chemical materials/components is received, are not recorded and/or checked for as per a written procedure.

OBSERVATION 9

Criteria for Beyond Use Dates (BUDs) assigned to drug formulations produced by your pharmacy are not formally and appropriately established in a written procedure nor supported with cited literature references and/or stability studies. For example, no cited literature or other evidence was provided in support of a BUD of 60 days for a phenobarbital suspension 6mg/mL (Rx (b) (6)).

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