DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE, Suite 210 Bothell, WA 98021 425-302-0340 Industry Information: www.fda.gov/oc/industry	9/19/2018-9/28/2018* FEI NUMBER 3014481174

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gregory A. Maag, Owner/Pharmacist

FIRM NAME	STREET ADDRESS
Maag Prescription Center LLC	333 W Center St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pocatello, ID 83204-3243	Producer of non-sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Your firm used non-pharmaceutical grade components that are not intended for drug production in the formulation of drug products.

Specifically, examples of non-pharmaceutical grade components used are:

A. (b) (4) (b) (4) in (b) (4) purchased from a retail grocery store. Your Pharmacist's Compounding Logs from 6/29/18 and 9/18/18 show over (b) (4) batches of drugs formulated with (b) (4) (b) (4).

1. Examples of drugs formulated with (b) (4) (b) (4) produced for individually identified patients are:

a. Glycopyrrolate 0.2 mg/mL oral suspension;
b. Budesonide 1mg/10mL oral suspension; and
c. Aminophylline 30mg oral suspension for animal use.

2. Examples of drugs formulated with (b) (4) (b) (4) produced for office stock are:

a. Trichloroacetic Acid 80% for topical use;
b. Potassium Hydroxide 10% Solution; and
c. Burrow's Solution for topical use.

B. (b) (4) (b) (4). Examples of drugs formulated using this component are:
1. Dexamethasone 24mg/mL Otic Solution; and
2. Lidocaine/Prilocaine 3.5% cream.

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	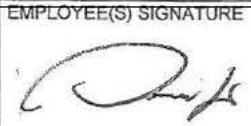	Tracy K. Li, Investigator	09/28/2018

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C. Potassium Hydroxide used in the formulation of Potassium Hydroxide 10% Solution.

OBSERVATION 2

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

Specifically, your firm's cleaning procedure is not adequate to decontaminate work surfaces and shared equipment for production of hazardous drugs to prevent cross-contamination. Your current practice for cleaning of shared production tools are done using household soap and water. Production tools are sprayed down with (b) (4) prior to use. Work surfaces are cleaned using (b) (4).

A. Your firm produced hazardous drugs without adequate cleaning between each hazardous drug. For example, on 9/13/18, your firm produced the following hazardous drugs:

- Progesterone/Testosterone cream (hormone), lot 4090538;
- Meloxicam/Topiramate/Tramadol HCl (opioid)/Propylene Glycol/Lidocaine cream, lot 4089507;
- Progesterone (hormone) Rapid Dissolve Tablets (RDT), lot 6134430;
- Estradiol/Estriol capsules (hormone), lot 8213284; and
- Fluorouracil cream (antineoplastic), lot 8213287.

B. Your firm (b) (4) produced non-hazardous drugs and hazardous drugs without first adequately cleaning shared production tools and production area to prevent cross-contamination. Additionally, your firm does not clean or replace gown, eye protection, and face mask, if worn during production to prevent cross-contamination. For example, on 9/13/18, your firm produced non-hazardous and hazardous drugs. The order of production, chronologically in the order as they appear in your Pharmacist's Compounding Log are:

- Aminophylline suspension, lot 8211646;
- Progesterone/Testosterone cream (hormone), lot 4090538;

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- Meloxicam/Topiramate/Tramadol HCl (opioid)/Propylene Glycol/Lidocaine cream, lot 4089507;
- Progesterone (hormone) Rapid Dissolve Tablets (RDT), lot 6134430;
- Estradiol/Estriol capsules (hormone), lot 8213284;
- Tadalafil RDTs, lot 8213138;
- Fluorouracil cream (antineoplastic), lot 8213287;
- Tadalafil RDTs, lot 8113229; and
- Metronidazole cream, lot 8211109.

OBSERVATION 3

Your firm lacks proper control to prevent contamination of drug products during production.

Specifically, on 9/20/18, the following were observed during the production of Metformin HCl 10% Topical cream; no lot number:

A. The operator touched his bare wrist with a red spatula and continued to use the same spatula to mix the product without first cleaning or replacing the spatula.

B. After production, work utensils and tools were washed using a scented household soap.

OBSERVATION 4

Mixing tools used in the production of drug products is not of appropriate design to facilitate cleaning and to prevent microbiological contamination of drugs.

Specifically, on 9/20/18, two spatulas used in the production of Metformin HCl 10% Topical cream was observed to be cracked on the wooden handle and had green discolorations on the handles. The screws connecting the wooden handle to the spatula appeared to be rusty.

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OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products. Specifically,

Your firm does not have scientific justification for the beyond use dates (BUD) for your non-sterile aqueous drug products that are stored at room temperature and distributed as office stock. Your current practice to assign BUDs is based on the literature, (b) (4) and discussions with your suppliers. There is either no stability data, or your BUDs exceeded those in the scientific literature that you use for drugs. Examples of the BUDs of aqueous drug products are:

- Trichloroacetic Acid 80% for topical use with BUD 12 months;
- Potassium Hydroxide solution with BUD 12 months; and
- Burrow's Solution for topical use with BUD 12 months.

**DATES OF INSPECTION
9/19/2018(Wed), 9/20/2018(Thu), 9/21/2018(Fri), 9/24/2018(Mon), 9/25/2018(Tue), 9/28/2018(Fri)

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