DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District Office 6th Ave. & Kipling St. Denver, CO 80225 303-236-3017 Industry Information: www.fda.gov/oc/industry	07/09/2018-10/24/18
	FEI NUMBER 3014435648

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Pujan A. Patel, Owner

FIRM NAME	STREET ADDRESS
Foothills Professional Pharmacy, Ltd.	4545 E. Chandler Blvd, Ste. 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Phoenix, AZ 85048	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:

~~The following are insanitary conditions or direct violations of section 503A of the Act.~~ → NLH 12/17/18

OBSERVATION 1
Your firm released finished products which failed potency testing.

Specifically,
A) Your firm produced and released the following sub-potent finished drug products:
- Lot 04172017:02@37; (C-T3) Liothyronine 62.5 mcg/capsule, test date 04/28/17 – assay 44.5%
- Lot 04172017:31@47NF; Testosterone 3 mg mini troche, test date 04/27/17 – assay 79.3%

B) Four bulk intermediates produced by your firm failed potency testing. Your firm used these bulk intermediates to produce and release approximately (b) (4) finished products. Most products were produced after receiving the failing test results. The sub-potent and super-potent bulk intermediates are:
- Lot 04032017:90@5; Liothyronine sodium (T3) 0.1%, test date 04/19/17 – assay 73.9%

-- Your firm used this bulk lot which failed potency to produce finished product lot 04172017:02@37 which also failed potency.
- Lot 04042017:72@1; Levothyroxine sodium (T4) 0.1%, test date 04/19/17 – assay 82.7%
- Lot 04242017:14@2; Liothyronine sodium (T3) 0.1% 1:1000/Triturate, test date 05/03/17 – assay 111%
- Lot 09292017:29@9; Liothyronine sodium 1:1000 Triturate, test date 10/06/17 – assay 131%

OBSERVATION 2
Your firm produced beta-lactam and non-beta-lactam drug products using shared equipment and utensils. There was inadequate containment and segregation to prevent cross-contamination.

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Specifically,
A) We observed apparent loose powder and dried product splatter inside hoods within every production room while technicians produced drug products.

B) We observed apparent loose powder and a semi-dry, smeared substance on multiple spatulas, mixing blades, and mixing containers for cream production which were designated clean.

C) We observed loose powder and a dry, white substance on equipment used to (b) (4) produce capsules and retail gift cards used to scrape powder into capsules. The items were designated clean.

D) Mixing cups for the household brand blender were damaged and discolored. Technicians use household brand (e.g., (b) (4)) blenders to crush tablets and homogenize powders for capsule products.

E) (b) (4) mixing blades used for cream production contained multiple cracks. There was discoloration inside the cracks. The cracks potentially shield microorganisms from cleaning agents.

F) We observed the worn, wooden handle of a spatula touching a metal (b) (4) . An operator used the (b) (4) to scoop raw material powder during production. The wooden handle was cracked and not smooth which might shield particles from cleaning agents.

OBSERVATION 3
Your firm does not use adequate disinfectant agents in production areas.

Specifically, the manufacturer label for (b) (4) reads in part, "Not for sanitization or disinfection. To sanitize and disinfect, use (b) (4) ". We observed a solution of (b) (4) used in all production areas to wipe spatulas which are direct product contact surfaces. The (b) (4) solution is the primary cleaning and decontamination agent used to wipe equipment, utensils, and the inside of hoods used for production.

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~~The following are deviations from CGMP applicable to products not afforded the exemptions from Section 503A of the Act.~~ NLH 12/17/18

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm has not performed assay testing on any finished products produced for office use. The following office use products were not analyzed for active ingredient content:

- Prescription (b) (6) , lot 04022018:07@77, C-Lidocaine/Tetracaine/Phenylephrine in Poly-Poloxamer 23%/7%/0.8% gel, produced 04/04/2018, and released 04/06/2018
- Prescription (b) (6) , lot 04022018:98@43, C-Benzocaine/Lidocaine/Tetracaine/ Phenylephrine 20/6/4/0.5% Versabase, produced 04/04/2018, and released 04/06/2018

OBSERVATION 5

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there is no specification for mixing time, and production personnel do not document the actual mixing time in production worksheets. There is no mixing time documented for the following topical products produced for office use:

- Prescription (b) (6) , lot 04022018:07@77, C-Lidocaine/Tetracaine/Phenylephrine in Poly-Poloxamer 23%/7%/0.8% gel, produced 04/04/2018, and released 04/06/2018
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OBSERVATION 6
Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, production personnel used a (b) (4) labeled as "(b) (4) to mix office-use prescription (b) (6) lot 0402018:06@48, C-Ultraskin Cream AM SPF 15, produced 04/05/18. There is no assessment of suitability for use to manufacture drug products. The (b) (4) has never been calibrated, and the manufacturer label indicates it was manufactured in 2011.

OBSERVATION 7
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the shelf-life assigned to office use products is not based on information generated from representative samples analyzed using validated test methods. There is no stability information for the following office use products:
• Prescription (b) (6) lot 04022018:07@77, C-Lidocaine/Tetracaine/Phenylephrine in Poly-Poloxamer 23%/7%/0.8% gel, produced 04/04/2018, released 04/06/2018, BUD 05/04/18
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OBSERVATION 8
Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm does not have a microbial limit specification for office use drug products and does not perform microbiology testing. The following office use products were not examined for microbiological quality:
• Prescription (b) (6) lot 04022018:07@77, C-Lidocaine/Tetracaine/Phenylephrine in Poly-Poloxamer 23%/7%/0.8% gel, produced 04/04/2018, and released 04/06/2018

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OBSERVATION 9

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, the following office use drug products do not have a documented date of final review and approval by a pharmacist:

• Prescription (b) (6) lot 04022018:07@77, C-Lidocaine/Tetracaine/Phenylephrine in Poly-Poloxamer 23%/7%/0.8% gel, produced 04/04/2018, and released 04/06/2018

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