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., Bldg 20 Denver, CO 80225 Industry Information: www.fda.gov/oc/industry	09/27/21-10/01/21
	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 Phoenix, AZ 85048	TYPE OF ESTABLISHMENT INSPECTED 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
Hazardous and non-hazardous drugs were produced without providing adequate cleaning of work surfaces and utensils to prevent cross-contamination. Specifically,

A) I observed residue and loose powder on two stainless steel bowls used with the (b) (4) in the hazardous production laboratory on 09/27/21. The bowls were designated as clean. The laboratory manager stated personnel use the (b) (4) to mix bulk lots greater than about (b) (4) g. Production records indicate the (b) (4) (b) (4) was used to produce cholesterol/lovastatin cream, lot 09242021:32@3 on 09/24/21.
-This is a repeat observation.

B) (b) (4) solution, lot (b) (4), in spray bottles labeled as (b) (4) ppm did not contain a (b) (4) ppm solution. The master and batch production record required personnel use (b) (4) mL of (b) (4)% (b) (4) (b) (4) to produce (b) (4) mL of (b) (4) ppm bulk solution, but the active ingredient label indicates personnel used (b) (4)% (b) (4). The actual concentration of lot (b) (4) is approximately 4870 ppm instead of (b) (4) ppm. Your approved procedure requires (b) (4) ppm (b) (4) solution for deactivation, decontamination, and sporicidal disinfection. I observed personnel use the solution throughout the production areas on 09/27/21. The procurement manager estimated your firm used (b) (4)% (b) (4) solution since June 2021.
- This is a repeat observation.

C) There was clear packing tape covering the opening of the approximate 5-inch-wide port on the right wall of Hood (b) (4) The adhesive side of the tape was open to the interior of the hood, and there was apparent white powder visible on the adhesive. Airflow moves inward over the work surface and up toward the HEPA filter. Examples of drugs produced inside this hood include naltrexone capsules, lot 09222021:82@82; pimobendan capsules, lot 09222021:45@60; and chromium picolinate/7-keto DHEA, lot 09202021:77@54.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Nicholas L. Hunt -S Digitally signed by Nicholas L. Hunt -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001722211, cn=Nicholas L. Hunt -S Date: 2021.10.01 12:25:37 -07'00'	Nicholas L. Hunt, Investigator	10/01/2021

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."