DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	7/2/2021-8/12/2021* FEI NUMBER 3009712882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kenneth L. Hughes, RPh, Co-Owner & President	
FIRM NAME Prescription Labs Inc dba Greenpark	STREET ADDRESS 4061f Bellaire Blvd
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77025-1121	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and 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 OBSERVED:

OBSERVATION 1

Personnel engaged in aseptic processing were observed with exposed skin.

Specifically, on 7/2/2021, I observed your pharmacy technician while aseptically processing the sterile drug product, Vancomycin-PF Ophthalmic 1.5% 10ML Soln, Lot # (b) (4), BUD 7/30/2021, Qty (b) (4) units break the plain of the ISO 5 LAFU, exposing (b) (6) facial skin while wearing a non-sterile hairnet, non-sterile eyeglasses, and non-sterile face mask inside the ISO 5 LAFU, which may directly affect drug quality. **This is a repeat observation.**

OBSERVATION 2

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, during a review of selected 3rd Party Contract Laboratory Sample Results, I found your pharmacy failed to reject out of specification products before and after dispensing them to patients and dispensed the drug product after the beyond use date. Additionally, your pharmacy continued to dispense after laboratory OOS results were received. For example:

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A. Sample ID - Sample_(b) (4) , Chlorhexidine 0.02% Ophthalmic, Lot #(b) (4) , Assay exceed specification ((b) (4)) Actual results (b) (4) Retest) (Test Date: 11/17/2020), (b) (4) (Retest) (Test Date: 11/20/2020), (b) (4) Test Date: 11/16/2020), & (b) (4) (Average) Test Date: 11/16/2020)) (Laboratory Received 11/12/2020), BUD 2/22/2021) Prescriptions dispensed from lot include:
   a. (b) (6), Dispensed Date: 10/22/2020
   b. , Dispensed Date: 9/30/2020
   c. , Dispensed Date: 9/8/2020
   d. , Dispensed Date: 9/16/2020
   e. , Dispensed Date: 9/4/2020
   f. , Dispensed Date: 10/1/2020
   g. , Dispensed Date: 10/7/2020
   h. , Dispensed Date: 11/23/2020

B. Sample ID- Sample_(b) (4) , Tacrolimus PF 5ml Aqueous Ophthalmic suspension 0.02%, Lot #(b) (4) , specification ((b) (4)), Actual Results (b) (4) (Actual (b) (4)) (Laboratory Test Date: 7/16/2020), BUD 10/24/2020. Pharmacy dispensing patient-specific prescriptions include:
   a. (b) (6) , Dispensed Date: 6/26/2020

C. Sample ID - (b) (4) _LabReport (2), Spironolactone Ophthalmic Solution, Lot # (b) (4) , Laboratory Received 8/27/2020/ Laboratory Test Completed: 10/10/2020, specification ((b) (4)), Results (b) (4), BUD 2/20/2021. Pharmacy dispensing patient-specific prescriptions include:
   a. (b) (6), Dispensed Date: 8/20/2020
   b. , Dispensed Date: 8/25/2020
   c. , Dispensed Date: 8/27/2020
   d. Dispensed Date: 10/21/2020
   e. Dispensed Date: 10/16/2020
   f. Dispensed Date: 9/4/2020
   g. Dispensed Date: 9/3/2020

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h. (b)(4) additional patient-specific prescriptions dispensed prior to test completion date

D. Sample ID - (b) (4) _LabReport, Mitomycin Ophthalmic Syringe Solution, Lot # (b) (4), Laboratory Received 6/28/2021/ Laboratory Test Date Completed: 7/9/2021, Specification ((b) (4)), Results (b) (4), BUD 6/4/2021. I found the pharmacy dispensed the drug product 20 days after the BUD. Pharmacy dispensing patient-specific prescriptions include:

a. (b) (6), Dispensed Date: 6/24/2021

OBSERVATION 3

Failing to conduct post-use (b) (4) integrity testing on (b) (4) used to sterilize products.

Specifically, your pharmacy failed to perform a (b) (4) test on all sterile (b) (4) used to render the drug product, Spironolactone-PF-Ophth Each 15ML, 0.005 MG/ML Soln of 770ML, Lot # (b) (4), BUD1/26/2022 sterile. For example, your pharmacy uses (b) (4) . Your formula worksheet fail to list the (b) (4) and upon completion of aseptic processing perform a (b) (4) test to ensure (b) (4) integrity. Spironolactone-PF-Ophth other sterilization steps after the (b) (4). Your pharmacy has processed (b) (4) different batches ((b) (4) units) over the past 12 months which the (b) (4) was not tested. **This is a repeat Observation**.

OBSERVATION 4

No assurance that sterile drug products were processed and stored under ISO 5 quality air.

Specifically,

A. On 8/2/2021 while visually observing your pharmacy technician aseptically process the drug product, Spironolactone-PF-Ophth Each 15ML, 0.005 MG/ML Soln of 770ML, Lot # (b) (4), BUD1/26/2022, dropper container kit packages and bottles were observed

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blocking the return vent in the ISO 5 LAFU while the technician was aseptically (b) (4) the Spironolactone-PF Ophthalmic and then transferring to the eye dropper bottles.

B. On 8/2/2021, I observed sterile (b) (4) used to render the drug product, Spironolactone-PF-Ophth Each 15ML, 0.005 MG/ML Soln was hanging from the ISO 5 LAFU in a manner that would prevent the movement of first pass air.

C. Tacrolimus-PF Aqueous Ophthalmic 5ML 0.2% Suspension processing includes (b) (4) preventing the movement of first pass air. Tacrolimus-PF Aqueous Ophthalmic does not undergo other sterilization steps after the (b) (4), there is no further sterilization step to the process.

OBSERVATION 5

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational conditions. For example, on July 15, 2021, your pharmacy failed to recertify the airflow, air quality, and performed no environmental monitoring prior to resuming aseptic production; resulting from the replacement of the (b) (4) AC unit designated for the entire cleanroom and ISO 5 LAFU built into the room (non-standalone unit); where aseptic processing occurs. The designated AC unit provides both the make-up air and cooling for all areas of the cleanroom. Your firm management reported only cleaning occurred with no justification for not performing a recertification prior to resuming aseptic production activities.

OBSERVATION 6

The facility design was observed to allow the influx of poor quality air into a higher classified area.

Specifically,

A. No HEPA filter coverage is available for the (b) (4) located in cleanroom for Suite (b) (4) Room) and Suite (b) (4) Room) (b) (4)

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cleanrooms containing LAFU and BSC, which may potentially allow the influx of poor quality air into a higher classified area. Furthermore, there are spaces between and edges of the doors.

B. (b) (4) doors are designed with no continuous monitoring and no alarms in place to notify of changes in differential pressure in the event both doors are opened simultaneously along with spaces between and edges.

OBSERVATION 7

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, your pharmacy failed to establish procedures for the deactivation of hazardous drug components used in the production of sterile and non-sterile drug products. For example:

A. Your pharmacy produced the sterile drug product, (b) (6), Testosterone Cypionate in Sesame Oil Injection, 10ML 200mg/ML Solution within Cleanroom Suite [b]. Your pharmacy also uses the same aseptic process suite for other non-hazardous drug products. Your pharmacy president and technician reported no special cleaning practices other than using sterile (b) (4) (b) (4) and (b) (4). The sterile [(b) (4)] is used (b) (4). No deactivation agents are used.

B. Your pharmacy produced the non-sterile drug product, Biestrogen (50/50) 1.8MG/ML 0.18% Cream, Lot # (b) (4), BUD1/12/2022 in the same non-sterile production area as the drug product, (b) (6), Clobetasol in (b) (4) each 60GM 0.05% CREAM, Lot # (b) (4), BUD 10/2/2021. Your pharmacy technician reported no special cleaning agents/practices are used to deactivate hazardous drug components. [(b) (6)] reported the pharmacy uses only [(b) (4)] non-sterile [(b) (4)] to clean surfaces, utensils, and equipment. [(b) (6)] continued in stating utensils may be washed using (b) (4).

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OBSERVATION 8

You did not appear to use biological indicators (BI) during (b) (4) and (b) (4) of finished drug products. Consequently, it is unclear if the sterilization conditions are adequate for inactivating all potential microbial contamination.

Specifically, your pharmacy utilizes (b) (4) without the use of bio indicators. For example, no bio indicators were used while (b) (4) the drug product, (b) (6), Testosterone Cypionate in Sesame Oil Injection 10ML 200mg/ml SOLN, Lot # (b) (4), BUD 11/1/2021; Atropine Sulfate Ophthalmic 10ML .2% Solution, Lot # (b) (4), BUD 9/27/2021; and (b) (6), Hydroxyprogesterone in Sesame Oil Injection 5ML MDV* 250MG/ML SOLN, Lot # (b) (4), BUD 11/23/2021.

OBSERVATION 9

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your pharmacy employees' media fill reports dated 2/1/2021 and procedure, "Personnel Aseptic Media Fill Testing and Process, P-402.2", Section 6.2, Sample Procedure for High Risk Level Compounding; failed to adequately represent your pharmacy's most complex aseptic manipulation activity. For example, your pharmacy's media fill procedure failed to include representative manipulation activities, documented within the sterile drug product, Acetylcysteine Ophthalmic each 10ML 10%Soln, Lot # (b) (4), BUD 9/21/2021, which was dispensed to patient-specific prescription, (b) (6). Media fill simulation selection are to represent the most difficult aseptic manipulations and most interventions, which has the potential of introducing microbials and/or alter the final drug quality through stressing the aseptic technique and ISO 5 processing area. Acetylcysteine Ophthalmic each 10ML 10%Soln has a batch sizes of (b) (4) units, whereas your pharmacy's media fill procedure, Personnel Aseptic Media Fill Testing and Process, P-402.2 for aseptically processing requires only (b) (4) units.

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OBSERVATION 10

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational (dynamic) conditions for your pharmacy's documented recertification report for the ISO 5 LAFU and ISO 5 BSC dated 8/9/2021.

*DATES OF INSPECTION

7/02/2021(Fri), 7/06/2021(Tue), 7/07/2021(Wed), 7/13/2021(Tue), 7/14/2021(Wed), 7/15/2021(Thu), 7/16/2021(Fri), 7/19/2021(Mon), 8/02/2021(Mon), 8/12/2021(Thu)

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