DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	10/16-20; 23-24; 27/17
	FEI NUMBER 3009712882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Kenneth L. Hughes, co-owner and President

FIRM NAME	STREET ADDRESS
Prescription Labs, Inc. dba Greenpark Compounding Pharmacy	4061F Bellaire Blvd.
CITY, STATE AND ZIP CODE Houston, TX 77025-1121	TYPE OF 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)/(WE) OBSERVED:

OBSERVATION #1

On 10/17/17, an operator engaged in aseptic processing was observed with his upper torso inside the ISO 5 area with partially exposed skin while wearing a non-sterile mask, goggles, and hairnet.

OBSERVATION #2

On 10/17/17, an operator was observed sanitizing his gloved hands with non-sterile (b) (4) and then resuming aseptic processing in the ISO 5 area.

OBSERVATION #3

The wipes used for disinfecting the interior of the ISO 5 hood are not sterile.

OBSERVATION #4

The ISO 5 classified areas were not certified under dynamic conditions. Specifically, unidirectional air flow was not verified under operational conditions.

OBSERVATION #5

There is no evidence that (b) (4) testing is being performed for sterile products. For example,

A. Tacrolimus Aqueous Ophthalmic 10ml 0.03% Suspension, lot #08312017@45 (Production date: 8/31/17 Beyond Use date: 12/29/17) was sterilized using a (b) (4) . There was no evidence that the (b) (4) (b) (4) test was performed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown	Stephen D. Brown, Investigator	10/27/2017

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OBSERVATION #6

The use of the sporicidal disinfectant, (b) (4) , in the ISO 5 areas is inadequate in that the contact time of (b) (4) minutes has not been substantiated.

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