DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	07/08-12, 15-17/2019
	FEI NUMBER 3015147067

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Beau Diab, RPh, Co-Owner and President

FIRM NAME	STREET ADDRESS
D&D Pharma, LLC dba MedScript Compounding Pharmacy	14450 Getz Rd, Suite 200
CITY, STATE AND ZIP CODE Noblesville, IN 46060	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

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

OBSERVATION 1

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, during environmental sampling of classified cleanroom suites on 05/30/2019, the following were recovered from ISO 5 laminar flow hoods:

-1 cfu/m3 during fungal air testing, identified as Geotrichum sp. at "(b) (4) ", referring to the hood on the (b) (4)
-1 cfu on a fungal contact plate, identified as a non-sporulating fungus at "(b) (4) ", referring to the hood on the (b) (4)

Several of your employees verbally confirmed that a retrospective investigation into potentially affected lots made in these hoods was not performed.

OBSERVATION 2

(b) (4) testing to the (b) (4) was not performed.

Specifically, the gauge used to measure pressure on the (b) (4) tester was last calibrated on 10/26/2017. We observed this gauge being used during a (b) (4) test of a (b) (4) used during production of lot number 07082019%383@3, product ESC01: epinephrine HCl (PF/SF)/lidocaine HCl (PF) in BSS 0.025%/0.75%.

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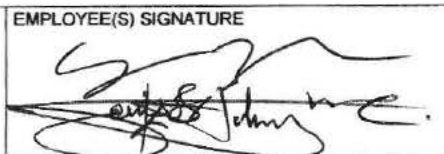
	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE		Charles L. Zhou, Investigator Michael Y. Philopoulos, Investigator Lewis K. Antwi, Investigator	07/17/2019

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OBSERVATION 3
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

a.Sterile lint-free wipes are stored outside the ISO 5 laminar flow hood, on top of the hood. These wipesare exposed to the ISO 7 environment. During production on 07/08/2019, these wipes were placed inside the ISO 5 laminar flow hood without being sprayed with sterile(b) (4) and sterile syringes were placed on top of these wipes.

b.During production of several batches on 07/09/2019, the Pharmacy Technician transferring materialsto the cart in the material entry room sprayed various materials with sterile (b) (4) but did not cover all surfaces with(b) (4) . Materials include vials of sterile (b) (4) , individually-wrapped needles, and individually-wrapped sterile(b) (4) wipes. The cart containing these materials were carted into Suite(b) (4) ISO 7) and the materials were transferred into the ISO 5 laminar flow hood and used in production.

OBSERVATION 4
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational conditions. Your firm's Pharmacist-in-Charge reported that when recertification of the cleanrooms was performed on or around (b) (4) , dynamic conditions were simulated by the recertification company employees by moving their hands inside the hood and walking around the room.

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	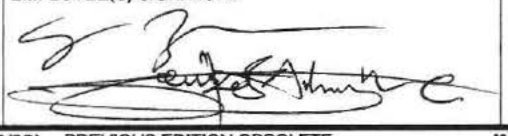	Charles L. Zhou, Investigator Michael Y. Philopoulos, Investigator Lewis K. Antwi, Investigator	07/17/2019