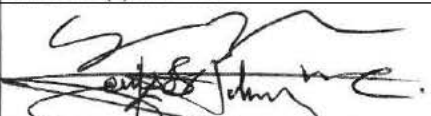


| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION | | | |
|---|---|---|-------------|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry | | DATE(S) OF INSPECTION 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 D&D Pharma, LLC dba MedScript Compounding Pharmacy | | STREET ADDRESS 14450 Getz Rd, Suite 200 | |
| CITY, STATE AND ZIP CODE Noblesville, IN 46060 | | 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 | | | |
| 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/m ³ 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%. | | | |
| Add Continuation Page | | | |
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) | DATE ISSUED |
| |  | Charles L. Zhou, Investigator Michael Y. Philopoulos, Investigator Lewis K. Antwi, Investigator | 07/17/2019 |

**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 | | 07/08-12, 15-17/2019 |
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| | | 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 | TYPE OF ESTABLISHMENT INSPECTED | |
| Noblesville, IN 46060 | Producer of sterile and non-sterile drugs | |

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 wipes are 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.

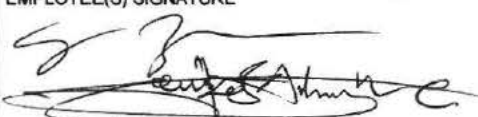
b. During production of several batches on 07/09/2019, the Pharmacy Technician transferring materials to the cart in the material entry room sprayed various materials with sterile (b) (4) but did not cover all surfaces with (b) (4). Materials include vials of sterile (b) (4), individually-wrapped needles, 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.

Add Continuation Page

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