U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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www.fda.gov

March 5, 2020

UPS NEXT DAY
SIGNATURE REQUIRED

Ref: WA# 282177

Laura Turner, Director
c/o Jody Edens, Assistant Board Director
Indiana Board of Pharmacy
402 W Washington St, Room W072
Indianapolis, IN 46204-2739

Dear Laura Turner:

The purpose of this letter is to refer to the Indiana State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Indiana BOP, D&D Pharma, LLC d/b/a MedScript Compounding Pharmacy, located at 14450 Getz Road, Suite 200, Noblesville, IN 46060-3303 (Pharmacy license # 60006594A and Controlled Substances Registration license # 60006594B).

FDA inspected the firm from July 8, 2019, to July 17, 2019. Indiana BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/132334/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by D&D Pharma, LLC d/b/a MedScript Compounding Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigators observed deviations from appropriate

sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. All materials were not adequately disinfected prior to entering the ISO 5 aseptic processing area.
2. Smoke studies of the ISO 5 aseptic processing area were not performed under dynamic conditions representative of actual processing.

D&D Pharma, LLC d/b/a MedScript Compounding Pharmacy committed to FDA in its August 6, 2019, written response and subsequent correspondence to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Indiana State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have any further questions, please feel free to contact Brett R. Havranek, Compliance Officer, at 913-495-5189, or via email at ORAPHARM3_RESPONSES@FDA.HHS.GOV.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2020.03.05 10:21:49 -05'00'

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III
Office of Regulatory Affairs
U.S. Food and Drug Administration

Cc: Grant Dino and Beau Diab, Co-Owners
D&D Pharma, LLC d/b/a MedScript Compounding Pharmacy
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Noblesville, IN 46060