U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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February 11, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Cheryl Wykoff Pezon
Michigan State Board of Pharmacy
Bureau of Professional Licensing/Licensing Division
611 W. Ottawa, 3rd Floor
P.O. Box 30670
Lansing, MI 48909-8170

Dear Ms. Pezon:

The purpose of this letter is to refer to the Michigan 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 Michigan BOP, Diplomat Pharmacy Inc., dba Diplomat Specialty Pharmacy, located at 4100 South Saginaw Street Flint, MI 48507-2687 (pharmacy license #5301008622).

FDA inspected the firm from October 31, 2017, to November 17, 2017. The FDA investigators were accompanied by a Michigan State investigator for one day. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm590759.pdf, 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. 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 Diplomat Specialty 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. In the response to the Form FDA 483, dated December 1, 2017, the firm advised FDA that it views "all inspections and audits as an opportunity to assess and improve upon our current practices."

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. Non-microbial contamination was in and adjacent to the ISO 5 area. Specifically, rust-colored residue and discolorations were observed within the firm's ISO 5 hoods and on the HEPA filter screens.

2. The firm used non-sterile cleaning wipes within the ISO 5 hoods.

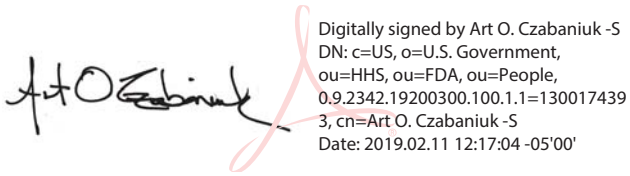
3. The firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Diplomat Specialty Pharmacy committed to FDA in its written responses dated December 1, 2017, and April 9, 2018, to correct the deviations 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 Michigan 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 additional questions, please contact Russell Riley, Compliance Officer, at (630) 323-2763 ext. 101, or by email at Russell.Riley@fda.hhs.gov.

Sincerely,



Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

cc: Brian Griffin
Chairman and CEO
Diplomat Pharmacy Inc., dba Diplomat Specialty Pharmacy
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Flint, MI 48507-2687