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ADMINISTRATION

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October 27, 2016

Caroline D. Juran, R.Ph., Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Maryland Drive, Suite 300
Henrico, VA 23233-1463

Dear Ms. Juran:

The purpose of this letter is to refer to the Virginia 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 Virginia BOP, RX South, LLC, dba RX3 Compounding Pharmacy, located at 12230 Iron Bridge Rd., Suite C, Chester, VA 23831-1534 (License # 0201003685).

FDA inspected the firm from April 11, 2016, to April 18, 2016. FDA investigators were accompanied by a Virginia state investigator for the first three days. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM499485.pdf

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by RX3 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 dispenses. In the response to the Form FDA 483, dated May 6, 2016, the firm advised FDA that it prepares human drugs "only after obtaining an individually-identifiable, patient-specific prescription from a duly licensed prescriber."

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. Specifically, brown stains were observed on the surface of the HEPA filter located in the ISO 5 laminar flow hood, and, what appeared to be rust was observed on the metal support structure beneath ISO 5 laminar flow hoods. In addition, the firm was not using a

sporicidal agent for disinfecting the ISO 5 laminar flow hoods. Furthermore, media fills are not performed to simulate the most challenging aseptic filling conditions.

RX3 Compounding Pharmacy committed to FDA in its response to the Form FDA 483[1], dated May 6, 2016, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the records, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Virginia 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 Ernie Bizjak, Compliance Officer, at 301-796-4081, or by email at Ernest.Bizjak@fda.hhs.gov.

Sincerely,

Evelyn Bonnin
District Director
Baltimore District Office

[1] See attached Form FDA 483 response letter dated May 6, 2016, from Christopher K. Currin, R.Ph., to Evelyn Bonnin, Baltimore District Director