U.S. FOOD & DRUG
ADMINISTRATION

New Jersey District
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January 3, 2017

VIA UPS OVERNIGHT

Anthony Rubinaccio, Executive Director
New Jersey State Board of Pharmacy
PO Box 45013
Newark, NJ 07101

Dear Mr. Rubinaccio,

The purpose of this letter is to notify the New Jersey State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection of a pharmacy licensed by the New Jersey BOP, Stokes Pharmacy, located at the time of the inspection, at 18000 Horizon Way, Suite 700, Mount Laurel, NJ 08504 (License #: 28RS00668300).

FDA inspected the firm from January 27, 2016, to February 12, 2016, after being contacted by the Drug Enforcement Agency (DEA) regarding the firm obtaining a Controlled Dangerous Substance License. The New Jersey BOP was informed of the inspection and accompanied the FDA investigator on January 27-28, 2016. 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/UCM488877.pdf.[1]

During the inspection, the FDA Investigator reviewed a small sample of records for products compounded by Stokes 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, which is consistent with traditional pharmacy practice. After review of the records and the firm's response to Form FDA 483 response, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. Please notify us if you

[1] Because you are an FDA commissioned official, you can request an unredacted copy of the Form FDA 483 and/or the firm's response to the Form FDA 483.

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 Barbara Wilimczyk-Macri, Compliance Officer, at (973) 331-4951.

Sincerely,

Craig W. Swanson
Acting District Director
New Jersey District Office