DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	01/27/2016 - 02/12/2016* FEI NUMBER 3002815949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Emmett McVey, RPh, Lead Pharmacist and Co-owner

FIRM NAME	STREET ADDRESS
Stokes Pharmacy	18000 Horizon Way Suite 700
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mount Laurel, NJ 08054	Producer of Drug Products

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 OBSERVED:

For the processing of drug products such as the human drug TRI-MIX Forte Injection Solution (Lot # 1207201@47 USE BY: 2/11/2016) and veterinary drugs Buprenorphine Injection Solution 0.5 MG/ML (Lot# 11242015@2 USE BY: 08/20/2016) and Tacrolimus AQ, Ophthalmic Solution (Lot # 12232015@8 USE BY: 6/20/2016):

Facilities and Equipment System

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, your firm aseptically processes sterile drug products, including injectables, in two ISO-5, positive-pressure, Laminar flow safety hoods located in the same ISO-7 cleanroom. The two hoods are placed at a 90 degree angle, about 10 feet apart, on adjacent cleanroom walls. One hood is used to process cytochemical drug products, such as those used to treat cancer. These types of drug products are typically processed under negative air pressure controls. The other hood is used to process most of your sterile drug products, which are not classified as cytochemicals.

The existing design controls create conditions conducive to drug product cross-contamination, with the more signifcant concern being the potential for cytochemical contamination of non-cytochemical drug products.

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your ISO-7 cleanroom contains items that are hard to clean and santize such as the three vinyl chairs with wheels and the two portable power strips on the floor with several electric power cords plugged into them.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	01/27/2016 - 02/12/2016* FEI NUMBER 3002815949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Emmett McVey, RPh, Lead Pharmacist and Co-owner

FIRM NAME	STREET ADDRESS
Stokes Pharmacy	18000 Horizon Way Suite 700
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mount Laurel, NJ 08054	Producer of Drug Products

Materials System

OBSERVATION 3

Written procedures are not followed for the identification, handling, and approval of closures.

Specifically, your firm uses two types of eye dropper tips, one is designed to dose aqueous formulations and one is designed with a larger orifice to dose oil based formulations. Your complaint files indicate that for at least one year your cleanroom personnel intermittently mismatched the dropper tips to the drug product formulations for Tacrolimus and Cidovoir eye drops for veterinary use. When oil based drug products accidentally received an aqueous tip you received complaints that the product was hard to dispense (e.g. complaint D150519-2, dated 5/19/2015). During the period between 04/07/2014 and 07/01/2015, your firm received at least eight complaints where you recorded complaint statements such as "drops are pouring out of the bottle...drops are coming out of the bottle too quickly...tacrolimus is coming out in stream instead of a drop" (e.g. Lots: 01142014@66; 03262015@8; 03042015@111; 04022015@1; 02022015@74 and 05012015@160).

Quality System

OBSERVATION 4

Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

Specifically, your procedures do not include provisions for filing Adverse Drug Events (ADE) reports. While reading through your complaint files at least one complaint (D 150206-2) was noted where you were required to file an ADE Report, and one was not filed. On 02/06/2015, your firm received a complaint that a cat died after being administered Buprenorphine 0.5 MG/ML Injection, Lot # 05302014@29, Exp. 02/24/2015.

Additionally, your Complaint Handling SOP Number 5.030 (Version 1.0 Effective 02-27-10) does not establish a system for recognizing and trending complaints that are indicative of product or process control deficiencies, such as the repeated use of the wrong dropper tips as cited above under observation #3.

*** DATES OF INSPECTION:**
01/27/2016(Wed), 01/28/2016(Thu), 02/01/2016(Mon), 02/02/2016(Tue), 02/08/2016(Mon), 02/12/2016(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Russell J. Glapion, Investigator Russell Glapion	02/12/2016