

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration 555 Winderley Place Suite 200 Maitland, FL 32751 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 5/15-18/2017
	FEI NUMBER 3004358166

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: James G. Castillo, President

FIRM NAME Tiberius, Inc. dba Custom Scripts Pharmacy	STREET ADDRESS 27732 Cashford Circle
CITY, STATE AND ZIP CODE Wesley Chapel, FL 33544	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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) (WE) OBSERVED:

Observation 1:
Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, non-sterile drug preparations both oral and topical use (b) (4) and (b) (4) (b) (4) water rather than a purified USP grade water. Examples of these include:

- A. Magic mouthwash #50 ((b) (4)) lot A0913C19
- B. HQ 4% REG HC Pump ((b) (4)) lot E1517C9

Observation 2:
Hazardous and highly potent drugs were prepared and handled without providing adequate cleaning of work surfaces and reusable equipment such as spatulas, (b) (4), and the (b) (4) (b) (4) to prevent cross-contamination.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joanne E. King -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Joanne E. King, Investigator	DATE ISSUED 05/18/2017
	<small>Digitaly signed by Joanne E King S DN: cn=US, o=US Government, ou=HHS, ou=FDA, ou=People c=Joanne E King, S 0 9 2342 19200300 100 11-1300174867 Date: 2017.05.18 17:18:25 -0400</small>		

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Specifically, your operations include the preparation of non-sterile drug products that contain anti-neoplastic agents such as fluorouracil and hormones such as estriol using reusable equipment that was (b) (4) cleaned using (b) (4) water, (b) (4) and (b) (4). Working surfaces are wiped down using (b) (4). You do not have documentation do show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations are as follows:

A. The fluorouracil lot (b) (4) bulk drug substance was used to prepare 5-fluorouracil 5%/HC 1% cream lot 0716C13.

B. The estriol lot (b) (4) bulk drug substance was used to prepare estriol 1mg/gm VC cream lot E0517C10.

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		Joanne E. King, Investigator	05/18/2017