

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/02/2018-07/11/2017*
	FEI NUMBER 3010660340

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Kirk G. Peterson, President

FIRM NAME Drug Crafters, L.P.	STREET ADDRESS 5680 Frisco Square Blvd. Suite 1100
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CITY, STATE AND ZIP CODE Frisco, TX 75034	TYPE OF ESTABLISHMENT INSPECTED Producer to Sterile and Non-Sterile Drug Products
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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

Personnel engaged in aseptic processing failed to follow proper aseptic techniques.

Specifically,

On 07/02/2018, your firm's pharmacy technician failed to execute proper aseptic technique while producing your firm's sterile drug product, Vitamin C P/F 500mg/mL, 30mL volume, Lot #06282018@37, Beyond Use Date: 11/30/2018. I witnessed your pharmacy technician rest her elbows on the front of laminar airflow hood #1, ISO 5 environment, while producing said sterile drug product.

OBSERVATION 2

Personnel engaged in aseptic processing were observed with exposed skin.

Specifically,

On 07/02/2018, your firm's pharmacy technician presented exposed skin while producing your firm's sterile drug product, Vitamin C P/F 500mg/mL, 30mL volume, Lot #06282018@37, Beyond Use Date: 11/30/2018. Your pharmacy technician's skin surrounding her personal eyeglasses was exposed and her sterile gowning did not overlap while producing sterile drug products in your laminar airflow hood #1, ISO 5 environment.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jason R. Caballero -S <small>Digitally signed by Jason R. Caballero-D DN: cn=US, o=U.S. Government, ou=FDA, ou=FDA, c=US, email=jrcaballero@fda.hhs.gov, cn=Jason R. Caballero-D Date: 2018.07.11 12:07:00 -0500</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jason R. Caballero, Investigator	DATE ISSUED 07/11/2018
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***DATES OF INSPECTION**
 7/02/2018(Mon), 7/03/2018(Tue), 7/04/2018(Wed), 7/05/2018(Thu), 7/05/2018(Fri), 7/09/2018(Mon), 7/10/2018(Tue), 7/11/2018(Wed)

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jason R. Caballero, Investigator	DATE ISSUED 07/11/2018
	(This area is intentionally left blank for the signature and name of the employee.)		