

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 407-475-4700 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/3-2/5/20 & 2/7/20
	FEI NUMBER 3011103365

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Anish Chemparathy, R.Ph., Pharmacist in Charge & Owner

FIRM NAME A Chem Rx, LLC dba Cortez Drugs	STREET ADDRESS 12116 Cortez Blvd.
CITY, STATE AND ZIP CODE Brooksville, FL 34613	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile 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) (WE) OBSERVED:

Observation 1: Non-microbial contamination was observed in your production area.

Specifically, on 2/3/20, within the firm's Non-Sterile Suite ((b) (4) Hood, (b) (4)), the vent directly over the working surface was observed visually un-clean, shedding and to contain an unknown brown residue. According to your firm's Pharmacist in Charge/Owner, the vent has not been replaced in approximately two years (all non-sterile drug products are produced within this hood).

Observation 2: Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, on 11/25/19, your firm produced the following non-sterile drug products: Estradiol 0.1mg/g Cream, Rx (b) (6), Exp.: 90 Days (hazardous), Testosterone 1mg/mL Cream, Rx (b) (6), Exp.: 90 Days (hazardous) and Naltrexone 4mg Capsules, Rx (b) (6), Exp.: 180 Days (non-hazardous) within the (b) (4) Hood, (b) (4) without providing adequate containment, segregation, and/or cleaning of the work surfaces.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica L. Pressley -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jessica L. Pressley, Drug Specialist	DATE ISSUED 02/07/2020
	<small> Dig. fully signed by Jessica L. Pressley, S DRG 0-45 0-415 Government 00-0100 00-0100 09.2342.10.2003300.100.1.1-2000545847 cr-Jessica L. Pressley, S Date: 2020/02/07 08:33:13 -05:00 </small>		