

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 1/4/2017-1/13/2017*
	FBI NUMBER 3011759873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Kelby D. Gorman , Pharmacist In Charge

FIRM NAME MOORE'S COMPOUNDING PHARMACY	STREET ADDRESS 5945 McArdle Rd Ste 101
CITY, STATE, ZIP CODE, COUNTRY Corpus Christi, TX 78412-3491	TYPE 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 OBSERVED:
OBSERVATION 1**

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed.

Specifically,

Your firm's Standard Operating Procedures entitled, "REQUIRED GARB FOR NON-STERILE COMPOUNDING AREA" SOP Number 7.090, Version 1.0 Effective 11-01-14 states that "When compounding non-sterile preparations, sterile gloves should be worn. If non-sterile gloves are used, they must be disinfected with sterile (b) (4) or an appropriate disinfectant".

On January 4, 2017, I observed the firm's Certified Pharmacy Technician (CPT) (b) (6), (b) (7)(C) produce one batch containing (b) (4) capsules of Tri-Est Progesterone (b) (4) 1/200mg SR, Lot # 2017-01-03:63@16. The CPT placed (b) (4) (b) (4) and (b) (4) using (b) (6), (b) (7)(C) bare hands in the (b) (4) hood. (b) (6), (b) (7)(C) started compounding capsules approximately in May 2015 and stated that (b) (6), (b) (7)(C) was trained to (b) (4) with (b) (6), (b) (7)(C) bare hands then put on non-sterile gloves before (b) (4) From October 1, 2016 through December 31, 2016, approximately (b) (4) prescriptions for compounded capsules were prepared by the firm.

***DATES OF INSPECTION**
1/04/2017(Wed), 1/05/2017(Thu), 1/06/2017(Fri), 1/09/2017(Mon), 1/10/2017(Tue), 1/12/2017(Thu), 1/13/2017(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patty P Kaewussdangkul, Investigator <i>Patty P. Kaewussdangkul</i>	DATE ISSUED 1/13/2017
	<input checked="" type="checkbox"/> Patty P Kaewussdangkul Investigator Signed by: Patty P. Kaewussdangkul	