DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/25/2016-9/1/2016*
	FEI NUMBER 3011761505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Willam O. Moore , President and Owner

FIRM NAME	STREET ADDRESS
MOORE'S PHARMACY INC	200 S Rachal St
CITY, STATE, ZIP CODE, COUNTRY Sinton, TX 78387-2524	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

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically,

A large dead cockroach was observed inside of your drug production room approximately 6 feet from where your firm produces capsules.

Both live and dead pests were observed in your firm's pharmacy in the area where capsules are stored and counted into prescription bottles.

I observed a 1 foot by 1 foot hole cut in the roof of your drug production room, exposing insulation and uncontrolled warehouse above. No controls are in place to prevent foreign material or pests from entering the room through this hole.

Doors on your firm's production room do not prevent pests from entering the room, the main door used to enter and exit the room has a 1 inch gap under the length of the door. The rear door adjacent to where capsules are produced, has a ½ inch gap under the length of the door; this door leads to the warehouse space where people eat, use the bathroom and cardboard boxes are stored near the loading dock.

OBSERVATION 2

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Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

- Your firm failed to conduct potency testing of non-sterile finished products. From 5/24/2016 to 8/25/2016, your firm manufactured and dispensed about (b) (4) prescriptions of drug products. Your firm routinely places Beyond Use Date (BUD) of drug products at 180 days. The drug products were not routinely tested for potency to ascertain that the suitability throughout the Beyond Use Date.

- From 7/25/2015 to 7/13/2016, your firm sent no finished products produced to your contract laboratory for testing.

OBSERVATION 3

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically,

- Your firm has not established procedures, policies, controls, tests or examinations which assure that batches of progesterone containing capsules are produced to assure uniformity and homogeneity. Additionally, there is not a clear indication of how pharmacists are able to check formula worksheets to determine that produced drugs were mixed correctly assuring uniformity and homogeneity. For example Tri-est progesterone lot 2015-02-23@3 was checked and released prior to analysis by your contract laboratory. Three analysis of this lot's Estradiol potency were performed, resulting capsules returned 120.8%, 82.4% and 87.6% of expected levels.

- Your firm's Pharmacist in Change stated that the firm's policy is to (b) (4) of drug products, (b) (4) . Finished product testing at your firm's contract laboratory, from 12/17/2014 to 8/26/2016, shows only (b) (4) lots of finished products had been tested.

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Of those samples, 16 of (b)(4) had out of specification test results ((b)(4)%). Your firm continued to distribute drug products while 70% of finished product analysis performed, showed drugs being produced were sub or super potent:

- The highest being an Estrone sample assay results of 134% of expected, in Tri-Est Progesterone 1.5/100 mg capsules
- The lowest being Estriol reading at 56.7% of expected, in Bi-Est Progesterone 0.75 mg capsules

- From 5/6/2015 to 7/1/2016, your firm sent (b)(4) finished product samples for testing, 100% were found out of specification (Both sub and super potent analysis results).

- Your firm failed to conduct any investigation to determine the root cause of the out of specification assay results. Your firm could not provide documentation that any attempt was made to contact customers whom you had provided sub potent or super potent drugs. No CAPAs, investigations, or Recalls have been performed.

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

- There is no written process for addition, mixing and verification of chemicals on formula worksheets used by the firm to assure that manufactured drugs have the correct potency.

For example, on 8/25/2016 one of your firm's pharmacists checked and released Bi-Est Prodhea 0.625/50 mg/10 mg* AV Capsules, lot number 2016-08-25@2. During (b)(6), (b)(7)(C) review, (b)(6), (b)(7)(C) released the lot without ensuring that the batch was made to specifications including the order of addition of chemicals and controls designed to ensure appropriate mixing.

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The instructions on the formula worksheet describe a different process and equipment, from what I observed during the production of progesterone containing capsules. I asked the Pharmacy Tech responsible for production of this lot, why (b) (6), (b) (7)(C) didn't use the instructions provided on the formula worksheet (b) (6), (b) (7)(C) stated that the firm had (b) (4) (b) (4)

Formula worksheets for progesterone capsule production differ from actual production or do not include the order of mixing, duration of mixing, and equipment used for mixing.

- Written procedures for process controls designed to assure that manufactured drugs have the correct potency are not followed.

1) Your firm's SOPs for Patient Satisfaction SOP # 5.020 and Complaint Handling SOP # 5.030 were authorized, reviewed and signed off by your firm's Pharmacist in Charge. They detail the process for handling complaints related to drugs produced onsite. For example, your firm provided a (b) (6), (b) (4) with the drug, lidocaine/ tetracaine/prilocaine gel lot # 2016-08-17@8 for use in their practice. The (b) (6), (b) (4) returned the lot to you with a complaint of the (b) (4) flavor being overly strong. After receiving this complaint your firm did not follow SOPs to document or investigate if there was a problem with the batch which could have caused it to fail to meet its specifications.

2) Your firm's SOP for Corrective and Preventative Action (CAPA) Management SOP # 7.030 was authorized, reviewed and signed off by your firm's Pharmacist in Charge. It details a process control designed to assure that root problems are identified, investigated and corrected. In the last 21 months 70% of the finished products tested by your firm's contract laboratory failed to meet their potency specification. I inquired if a CAPA had been opened relating to these failures. According to your firm's Pharmacist in Charge, there have been no CAPAs and your firm does not currently follow this procedure.

3) Your firm's SOP for Recall of Compounded Product SOP # 7.080 was authorized, reviewed and signed off by your firm's Pharmacist in Charge. This SOP states that "In the event that a

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compounded product is suspected or confirmed to have caused patient harm, was compounded incorrectly, or needs to be recalled for any other reason, all facilities and/or patients that received the product must be notified immediately." It also lists "Test results from third party laboratory". Your firm's contract laboratory notified you that 13 lots, or 70.0% of what was provided to them, failed to meet their potency specification. Your firm's Pharmacist in Charge stated that the firm at this location has not performed a recall as per SOP 7.080; furthermore she was not able to provide documentation that those patients with sub or super potent drugs had been notified of the issues with their medications.

4) Your firm's SOP for Non-Sterile Compounding Process Validation SOP # 7.100 was authorized, reviewed and signed off by your firm's Pharmacist in Charge. It lists that "All deviations must be documented." for a formula worksheet to meet acceptance criteria. According to your firm's Pharmacy – Tech, since February 2016 you firm has regularly not documented process deviations related to the mixing of drug products including progesterone containing capsules.

OBSERVATION 5

Deviations from written production and process control procedures are not recorded and justified.

Specifically, during a review of your firm's batch records I observed that expired raw materials and drug substances were being used to produce drugs with Beyond Use Dates (BUD) of 180 days as well as other deviations from the batch record without documentation. For example:

- According to the manufacturer's COA, Estriol (b) (4) lot (b) (4) expired on 11/07/2015. On ~~12/11/2016~~ 12/11/2015 Sol 9/1/16, it was used in the production of Bi-Estrogen (b) (4) lot number (b) (4) which subsequently failed potency testing. This formula worksheet was checked by one of your firm's pharmacists, where (b) (6), (b) (7)(C) initials appear over the top of the expiration date over a month prior to the date of the check. The expired raw material was not discarded after this batch, it continued to be used in a total of (b) (4) lots after it had been expired. No deviations were noted on formula work sheets reviewed.

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Beyond use dates for products set by the firm are reportedly no more than 6 months or the date of the expiration of the active ingredient. Between 5/08/2015 and 3/07/2016, approximately (b) (4) lots of drug products were given 180 day BUDs, which exceeded the expiration of date of Estriol (b) (4) lot (b) (4) No deviations were noted on formula work sheets reviewed.

- According to the manufacturer's COA, Prilocaine (b) (4) lot number (b) (4) expiration date 11/19/2016 was used to produce Prilo/Tetra HCL/Lido lot 2016-08-17@8 BUD of 2/13/2017 for a (b) (6), (b) (7)(C) to use in their office. This product was returned for a complaint of overly (b) (4) flavor and Prilo/Tetra HCL/Lido lot 2016-08-19@5 BUD of 2/15/2017 was produced. On the formula worksheet for the lots above, your firm's pharmacist initialed and released the lots regardless of the BUD extending beyond the expiration dates of the Prilocaine. No deviations were noted on formula work sheets.

  Additionally, Prilo/Tetra HCL/Lido lot 2016-08-19@5's formula work sheet calculates that Flavor, (b) (4) should be (b) (4) . Your firm's Pharmacist Tech recorded that (b) (6), (b) (7)(C) used (b) (4) and initials of your firm's pharmacist next to the number indicates that (b) (6), (b) (7)(C) checked that the (b) (4) were correct. No deviations were noted on formula work sheet.

***DATES OF INSPECTION**
8/25/2016(Thu),8/26/2016(Fri),8/29/2016(Mon),8/30/2016(Tue),9/01/2016(Thu)

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