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	9/23/2019-10/3/2019*
	FEI NUMBER 3012906298

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig W. McAlister, Pharmacist-in-Charge & Co-Owner

FIRM NAME	STREET ADDRESS
MCALISTER DRUG CORPORATION	948 S Yukon Pkwy
CITY, STATE, ZIP CODE, COUNTRY Yukon, OK 73099-4589	TYPE 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 WE OBSERVED:

OBSERVATION 1

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your firm is using non-pharmaceutical grade materials to make drug products. For example,

a) Your firm uses (b) (4) in certain drug products whose formulation requires (b) (4) Your firm is also using the (b) (4) to make (b) (4) (b) (4) for use in certain drug products. Your firm does not perform testing (analytical or microbiological) to show the (b) (4) at least/at minimum meets the specifications for (b) (4) USP.

Examples of lots made using the (b) (4) made from (b) (4) include:

i. LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19.
ii. LIDO 20%/TETR 4%/PHENYL 2% made on 4/17/19, 4/30/19, 6/11/19, 6/26/19 and 8/12/19.

Examples of products made using the (b) (4) include:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO Shanna N Purdy, Investigator	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 10-03-2019 10:05:00	DATE ISSUED 10/3/2019

i. Itch Relief Gel made on 4/11/19, 6/24/19, 7/11/19 and 9/13/19.
ii. Aluminum Chloride Hex 20% Top Solution made on 6/27/19 and 8/15/19.
iii. Omeprazole 2mg/mL Suspension (Oral) made on 8/13/19 & 9/9/19.
iv. LIDO/BEN/ADRYL/HC/NYSTATIN/H2O SUSPENSION made on 9/17/19.
v. (b) (4) used to (b) (4) for the LIDO 20%/TETR 4%/PHENYL 2% made on 4/17/19, 4/30/19, 6/11/19, 6/26/19 and 8/12/19 and the LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19.

b) Your firm uses (b) (4) for making drug products. The (b) (4) is labeled "FOR TECHNICAL USE ONLY". (b) (4) Wart Solution made on 4/10/19 was made using this acetone.

c) Your firm uses (b) (4) (b) (4) for making drug products. For example,

i. Aluminum Chloride Hex 20% Top Solution made on 6/27/19 and 8/15/19.
ii. (b) (4) Spray w/Clobetasol 0.05%/Zinc 0.2% made on 5/21/19.
iii. Estriol .1% Cream made on 7/9/19.

d) Your firm used Sodium Hyaluronate (Cosmetic Grade) to make Hyaluronic Acid 10mg/gm Vaginal Gel on 6/20/19.

OBSERVATION 2
You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

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	9/23/2019-10/3/2019* FEI NUMBER 3012906298

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig W. McAlister, Pharmacist-in-Charge & Co-Owner	
FIRM NAME MCALISTER DRUG CORPORATION	STREET ADDRESS 948 S Yukon Pkwy
CITY, STATE, ZIP CODE, COUNTRY Yukon, OK 73099-4589	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

Specifically, your firm uses (b) (4) to clean work surfaces, utensils and equipment such as the (b) (4) used to make hazardous drug products. Your firm does not use a deactivating agent to ensure removal of residue in between batches of hazardous drugs to prevent cross contamination. Active pharmaceutical ingredients (API) used include testosterone, estradiol, 5-fluorouracil, DHEA, and progesterone.

OBSERVATION 3

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD)/expiration dates placed on all your drug products. For example,

a) Itch Relief Gel made on 4/11/19, 6/24/19, 7/11/19 and 9/13/19. This product is made with (b) (4) and is assigned an expiration date of 180 days.

b) LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19. This product is made with (b) (4) and is assigned an expiration date of 3 months.

c) LIDO 20%/TETR 4%/PHENYL 2% made on 4/17/19, 4/30/19, 6/11/19, 6/26/19 and 8/12/19. This product is made with (b) (4) and is assigned an expiration date of 180 days.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Shanna N Purdy, Investigator	X Margaret M Annes CSO Signed By Margaret M. Annes -S Date Signed 10-03-2019 10:05:00	10/3/2019

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	9/23/2019-10/3/2019*
	FEI NUMBER 3012906298

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig W. McAlister, Pharmacist-in-Charge & Co-Owner

FIRM NAME	STREET ADDRESS
MCALISTER DRUG CORPORATION	948 S Yukon Pkwy
CITY, STATE, ZIP CODE, COUNTRY Yukon, OK 73099-4589	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

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 does not conduct routine testing for potency for all drug products produced by your firm. Examples include the following,

a) Itch Relief Gel made on 4/11/19, 6/24/19, 7/11/19 and 9/13/19.

b) LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19.

c) LIDO 20%/TETR 4%/PHENYL 2% made on 4/17/19, 4/30/19, 6/11/19, 6/26/19 and 8/12/19.

OBSERVATION 5

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm does not perform external calibration of the analytical balances used to weigh ingredients, including active pharmaceutical ingredients (API), used to make drug products. Examples of lots made include the following:

i. PROMETH (A) 12.5MG/0.1ML PLOGEL made on 2/25/19.
ii. Itch Relief Gel made on 4/11/19, 6/24/19, 7/11/19 and 9/13/19.
iii. LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19.

OBSERVATION 6

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Shanna N Purdy, Investigator	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 10-03-2019 10:05:00	10/3/2019

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	9/23/2019-10/3/2019*
	FEI NUMBER 3012906298

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig W. McAlister, Pharmacist-in-Charge & Co-Owner	
FIRM NAME MCALISTER DRUG CORPORATION	STREET ADDRESS 948 S Yukon Pkwy
CITY, STATE, ZIP CODE, COUNTRY Yukon, OK 73099-4589	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

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,

a) LIDO 12.5%/TETR 12.5%/PRILO 3%/PHENYL 3% DENT made on 9/19/19. Your firm did not document on the formulation sheet, the lot of (b) (4) used. Your firm also did not document if the (b) (4) and the preparation of a (b) (4) solution, including the lot of (b) (4) used.

b) LIDO 20%/TETR 4%/PHENYL 2% made on 4/17/19, 4/30/19, 6/11/19, 6/26/19 and 8/12/19. Your firm did not document on the formulation sheet, the lot of (b) (4) (b) (4) used. Your firm also did not document if the (b) (4) and the preparation of a (b) (4) solution, including the lot of (b) (4) used.

***DATES OF INSPECTION**
9/23/2019(Mon), 9/24/2019(Tue), 9/26/2019(Thu), 9/30/2019(Mon), 10/03/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Shanna N Purdy, Investigator	X Margaret M Annes CSO Signed By Margaret M. Annes -S Date Signed 10-03-2019 10:05:00	10/3/2019