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	1/13/2020-1/24/2020* FEI NUMBER 3004549371

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Larry D. Brim, II, DPh, Pharmacist-in-Charge/Co-Owner

FIRM NAME	STREET ADDRESS
Claremore Compounding Center, Inc.	1151 N. Lynn Riggs Blvd
CITY, STATE, ZIP CODE, COUNTRY Claremore, OK 74017-3068	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 I OBSERVED:

OBSERVATION 1

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

Specifically, your firm is using orange food color that is non-pharmaceutical grade to make drug products. Examples include lot #95806 of hydrocodone/dextromethorphan 10mg/10mg capsules made on 12/10/19 and lot #94010 of hydrocodone/dextromethorphan 5mg/5mg capsules made on 9/11/19.

OBSERVATION 2

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) Lot #95371 of Dry Skin Moisturizing (OTC) 5% - 1% Cream (containing (b) (4) and hydrocortisone) made on 11/20/19 was assigned a BUD of 360 days.
b) Lot #94404 of CCC Cold Max 100-5-10-2mg per 5mL suspension (containing guaifenesin, phenylephrine HCl, chlorpheniramine Maleate and dextromethorphan hydrobromide) made on 10/1/19 was assigned a BUD of 180 days.
c) Lot #94402 of CCC Coughist PE 100-5-2mg per 5mL suspension (containing guaifenesin, phenylephrine HCl, and chlorpheniramine maleate) made on 10/1/19 was assigned a BUD of 180 days.
d) Jungle Juice Liquid (containing (b) (4) and lidocaine): Lot #92698 made on 7/9/19, lot #93496 made on 8/16/19, and lot #94749 made on 10/17/19 were each assigned a BUD of 360 days.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 01-24-2020 08:04:50	1/24/2020

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e) Jungle Ointment (containing (b) (4) hydrocortisone and lidocaine): Lot #92655 made on 7/5/19 and lot #92915 made on 7/19/19 were each assigned a BUD of 360 days.
f) Psoria-Stop (Coal Tar/HC) OTC 5%-1% Ointment (containing coal tar topical solution and hydrocortisone): Lot #92724 made on 7/10/19 and lot #94694 made on 10/15/19 were each assigned a BUD of 180 days.

OBSERVATION 3

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) Lot #95371 of Dry Skin Moisturizing (OTC) 5% - 1% Cream (containing (b) (4) and hydrocortisone) made on 11/20/19.
b) Lot #94404 of CCC Cold Max 100-5-10-2mg per 5mL suspension (containing guaifenesin, phenylephrine HCl, chlorpheniramine Maleate and dextromethorphan hydrobromide) made on 10/1/19.
c) Lot #94402 of CCC Coughist PE 100-5-2mg per 5mL suspension (containing guaifenesin, phenylephrine HCl, and chlorpheniramine maleate) made on 10/1/19.
d) Jungle Juice Liquid (containing (b) (4) and lidocaine): Lot #92698 made on 7/9/19, lot #93496 made on 8/16/19, and lot #94749 made on 10/17/19.
e) Jungle Ointment (containing (b) (4) hydrocortisone and lidocaine): Lot #92655 made on 7/5/19 and lot #92915 made on 7/19/19.
f) Psoria-Stop (Coal Tar/HC) OTC 5%-1% Ointment (containing coal tar topical solution and hydrocortisone): Lot #92724 made on 7/10/19 and lot #94694 made on 10/15/19.

***DATES OF INSPECTION**

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1/13/2020(Mon), 1/14/2020(Tue), 1/15/2020(Wed), 1/16/2020(Thu), 1/17/2020(Fri), 1/24/2020(Fri)

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